means prevents axial movement of the cartridge assembly relative to the doságe assembly.

- 45. The medication delivery device of claim 44, wherein the dosage assembly comprises a phunger means and a drive means and wherein the second coupling means is selected to ensure that uncoupling of the needle assembly from the dosage assembly does not result in movement of the plunger means relative to a removable carridge that is housed in the cartridge assembly.
- The medication delivery device of claim 45, wherein the first coupling means comprises a snap-lock means for allowing axial coupling and uncoupling of the needle assembly to and from the cartridge assembly without the need to rotate the needle assembly relative to the dosage assembly.
  - The medication delivery decide of claim 46, wherein the second coupling means comprises a threaded coupling and wherein the first coupling means is at least partially integrated into the needle assembly.
- 48. The medication delivery device of claim 47,/wherein the snap lock means is fully integrated into the needle assembly.

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#### REMARKS

Claims 1-13 and 19-33 have been canceled without prejudice or disclaimer. Claims 34-48 have been added and therefore are pending in the present application. Claims 34-48 are supported by the drawings, the original claims, and the specification.

It is respectfully submitted that the present amendment presents no new matter and places this case in condition for allowance. Reconsideration of the application in view of the above amendments and the following remarks is requested.

In the previous office action, the Examiner rejected claims 1, 19, 21-23 and 25-27 under 35 USC § 102(b) in view of Chanoch US Pat. No. 5,688,251 and rejected claims 28-33 under 35 USC § 103(a) in view of Chanoch. The Examiner dismissed the Applicants' previous arguments that their invention is novel and non-obvious because Chanoch does not disclose selection of a means for securing the needle to cartridge assembly and a means for securing the dosing assembly to the cartridge assembly such that the dosing assembly does not move relative to the cartridge assembly during removal or attachment of a needle. The Examiner has, ostensibly, taken the position that one of ordinary skill in the art would grasp the Chanoch cartridge assembly or both the Chanoch cartridge assembly and the Chanoch dosing assembly when removing or attaching a needle and therefore the dosing assembly would not move relative to the cartridge assembly during a needle change. The Examiner, also asserts that because Chanoch states that other means for mounting the needle cannula to the cartridge holder may be provided, it discloses that two different types of coupling means on a single device or that something other than threads as shown in the figures may be used.

Applicants note that even if the Examiner's view of Chanoch is correct, Chanoch does not disclose or even suggest a means for ensuring that the dosing assembly does not move relative to the cartridge assembly when the dosing assembly and the needle are intentionally grasped during a needle change. Chanoch is silent as to how and what criteria should be used when selecting a means for securing the needle assembly to the cartridge assembly and the cartridge assembly to the dosing assembly. Moreover, Chanoch fails to disclose or even suggest that the two securing means should be chosen so that when force is applied to remove (or attach) the needle while the

dosage assembly is grasped, the security of the dosage assembly to the cartridge assembly is not jeopardized.

As presently claimed in the new pending claims (i.e., claims 34-48), Applicants' invention specifically requires that the means for securing the needle to the cartridge assembly and the means for securing the cartridge assembly to the dosing assembly be chosen so that when the needle assembly and the dosing assembly are grasped and a force applied to both to remove (or attach) the needle assembly, the cartridge assembly remains securely fixed to the dosing assembly. Thus, it is irrelevant to the patentability of the present claims whether one would grasp the cartridge assembly during a needle change. By their own terms, the claims now require that when the dosing assembly and needle assembly are grasped during needle attachment or removal, the means for securing the dosing assembly to the cartridge assembly must prevent unintended axial movement of the dosage assembly relative to the cartridge assembly. By preventing the cartridge assembly from moving relative to the dosing assembly when changing a needle the accuracy of a subsequently administered dose can be guaranteed.

#### Conclusion

In view of the above, it is respectfully submitted that all claims are in condition for allowance. Early action to that end is respectfully requested. The Examiner is hereby invited to

contact the undersigned by telephone if there are any questions concerning this amendment or application.

Respectfully submitted,

Date: August 15, 2002

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Marc A. Began Reg. No. 48,829 Novo Nordisk of North America, Inc. 405 Lexington Avenue, Suite 6400 New York, NY 10174-6401 (212) 867-0123

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Attorney Docket No.: 5533.200-US

PATENT

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Buch-Rasmussen et al.

Application No.: 09/349,748

Group Art Unit: 3763

Filed: Feb. 11, 2002

Examiner: K. Sirmons

For: Medical Device

### AMENDMENT UNDER 37 C.F.R. 1.111

Commissioner for Patents Washington, DC 20231

Sir:

In response to the telephonic conversations between Examiner Sirmons and Marc A. Began (attorney for the Applicants) on Jan 16, 2003 and on Jan 21, 2003, please amend the above-captioned application as follows (a marked up version pursuant to 37 C.F.R. 1.21 is attached hereto, where applicable):

#### IN THE CLAIMS:

34. (Amended) A medication delivery device comprising:

- a cartridge assembly comprising a cartridge having a pierceable scal at one end and a moveable stopper at an opposite end;
- a dosage assembly comprising a plunger means for acting on the stopper; a mechanism for setting a specified dose; and a drive means for advancing the plunger means to deliver the specified dose;
- a needle assembly;
- a first coupling means for coupling and uncoupling the needle assembly to and from the cartridge assembly;

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a second coupling means for coupling and uncoupling the cartridge assembly to and from the desage assembly;

wherein the first coupling means comprises a snap lock; and wherein the second coupling means is selected such that when a user grasps the needle assembly and applies a force to couple it to and to uncouple it from the cartridge assembly, while simultaneously grasping the dosage assembly and applying an equal but opposite force thereto, the cartridge assembly cannot not move axially with respect to the dosage assembly.

The medication delivery device of claim 34, wherein the first coupling means comprises a means for coupling or uncoupling the needle assembly through an axial movement of the needle assembly relative to the cartridge assembly and the second means comprises a threaded means.

The medication delivery device of claim 35, wherein the cartridge assembly comprises a housing for receiving the cartridge and wherein the snap lock is an integral part of the needle assembly..

A medication delivery device upon which a needle assembly can be mounted, the device comprising:

- a cartridge assembly comprising a cartridge having a movable stopper at one end and a pierceable seal at an opposite end;
- a dosage assembly comprising a mechanism for setting a specified dose, a plunger means for abutting the moveable stopper, and a drive means for driving the plunger means to deliver the set doseage;
- a first coupling means for coupling and uncoupling the cartridge assembly to and from the dosage assembly; and
- a second coupling means for coupling and uncoupling a needle assembly to and from the cartridge assembly;

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wherein the first and second coupling means are selected so that when a user grasps the needle assembly and applies force to the needle assembly to couple and uncouple it from the device while simultaneously grasping the dosage assembly and applying a equal and opposite force to the dosage assembly, the dosage assembly cannot move relative to the cartridge assembly, thereby ensuring that the plunger means remains abutted against the stopper; and

wherein the first or second coupling means comprises a snap lock.

The medication delivery device recited in claim 21, wherein the second coupling means comprises a threaded coupling means and wherein the second coupling means comprises a means for coupling and uncoupling through an axial movement of the needle assembly relative to the cartridge assembly.

The medication delivery device of claim 37, wherein the first coupling means comprises a means for uncoupling through an axial movement of the cartridge assembly felative to the dosing assembly.

The medication delivery device of claim 37, wherein the first coupling means comprises a threaded coupling means.

The medication delivery device of claim/37, wherein the cartridge assembly comprises a housing to accommodate the cartridge and wherein the second coupling means comprises a means for axially coupling or uncoupling the needle assembly from the cartridge assembly.

The medication delivery device of claim , wherein the second coupling means comprises a threaded coupling means.

A medication delivery device comprising: a cartridge assembly comprising:

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a housing capable of housing a removable cartridge that has a pierceable seal at one end, is filled with medication, and has a moveable stopper at an opposite end that when moved toward the medication pressurizes the

a needle mounting means for mounting a needle on the cartridge assembly:

- a dosage assembly for delivering a set dose of medication, comprising:
  - a plunger means for moving the stopper, a dose setting means for setting a dose, and a drive means for driving the phanger means to deliver the set dose, wherein after a portion of medication is expelled from the
  - cartridge, the plunger means abuts the stopper;
- a first means for coupling and uncoupling a needle assembly to and from the cartridge assembly;
- a second means for coupling and uncoupling the dosage assembly to and from the cartridge assembly;

wherein the first and second coupling means are chosen so that when a user simultaneously grasps the dosage assembly and the needle assembly and applies a force to the needle assembly to couple (or uncouple) the needle to or from the device the cartridge assembly is positively precluded from moving axially relative to the cartridge assembly; and

wherein at least the first or the second coupling means comprises a snap lock.

A medication delivery device comprising:

- a cartridge assembly for housing a removable cartridge containing a medication;
- a needle assembly;
- a dosage assembly comprising a mechanism for setting a dosage less than the full amount of medication contained in the cartridge;
- a first coupling means for coupling and uncoupling the needle to and from a removable cartridge housed in the cartridge assembly; and

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a second coupling means for coupling and uncoupling the cartridge assembly to and from the dosage assembly;

wherein the first coupling means comprises a snap lock; and wherein the second coupling means is chosen so that when a user couples or uncouples the needle assembly from the cartridge by grasping the needle assembly and the dosage assembly simultaneously and applying force to both, the second coupling means prevents axial movement of the cartridge assembly relative to the dosage assembly.



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#### REMARKS

As per the Examiner's suggestion, the claims have been amended so that one of the coupling means comprises a snap lock. It is respectfully submitted that the present amendment presents no new matter and places this case in condition for allowance. Reconsideration of the application in view of the above amendments and the following remarks is requested.

#### Conclusion

In view of the above, it is respectfully submitted that all claims are in condition for allowance. Early action to that end is respectfully requested. The Examiner is hereby invited to

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contact the undersigned by telephone if there are any questions concerning this amendment or application.

Respectfully submitted,

Date: January 21, 2003

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Marc A. Began Reg. No. 48,829 Novo Nordisk 100 College Rd West Princeton NJ 08540 (212) 867-0123

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#### VERSION WITH MARKINGS TO SHOW CHANGES MADE

- 34. (Amended) A medication delivery device comprising:
  - a cartridge assembly comprising a cartridge having a pierceable seal at one end and a moveable stopper at an opposite end;
  - a dosage assembly comprising a plunger means for acting on the stopper; a mechanism for setting a specified dose; and a drive means for advancing the plunger means to deliver the specified dose;
  - a needle assembly:
  - a first coupling means for coupling and uncoupling the needle assembly to and from the cartridge assembly;
  - a second coupling means for coupling and uncoupling the cartridge assembly to and from the dosage assembly;

#### wherein the first coupling means comprises a snap lock; and

wherein the <u>first and</u> second coupling means are <u>is</u> selected such that when a user grasps the needle assembly and applies a force to couple it to and to uncouple it from the cartridge assembly, while simultaneously grasping the dosage assembly and applying an equal but opposite force thereto, the cartridge assembly cannot not move axially with respect to the dosage assembly.

- 35. The medication delivery device of claim 34, wherein the first coupling means comprises a means for coupling or uncoupling the needle assembly through an axial movement of the needle assembly relative to the cartridge assembly and the second means comprises a threaded means.
- 36. The medication delivery device of claim 35, wherein the cartridge assembly comprises a housing for receiving the cartridge and wherein the first coupling means comprises a snap lock and wherein the snap lock is an integral part of the needle assembly.



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- 37. A medication delivery device upon which a needle assembly can be mounted, the device comprising:
  - a cartridge assembly comprising a cartridge having a movable stopper at one end and a pierceable seal at an opposite end;
  - a dosage assembly comprising a mechanism for setting a specified dose, a plunger means for abutting the moveable stopper, and a drive means for driving the plunger means to deliver the set doseage:
  - a first coupling means for coupling and uncoupling the cartridge assembly to and from the dosage assembly; and
  - a second coupling means for coupling and uncoupling a needle assembly to and from the cartridge assembly:

wherein the first and second coupling means are selected so that when a user grasps the needle assembly and applies force to the needle assembly to couple and uncouple it from the device while simultaneously grasping the dosage assembly and applying a equal and opposite force to the dosage assembly, the dosage assembly cannot move relative to the cartridge assembly, thereby ensuring that the plunger means remains abutted against the stopper and

wherein the first or second coupling means comprises a snap lock.

- 38. The medication delivery device recited in claim 37, wherein the second coupling means comprises a threaded coupling means and wherein the second coupling means comprises a means for coupling and uncoupling through an axial movement of the needle assembly relative to the cartridge assembly.
- 39. The medication delivery device of claim 37, wherein the first coupling means comprises a means for uncoupling through an axial movement of the cartridge assembly relative to the dosing assembly.

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- 40. The medication delivery device of claim 37, wherein the first coupling means comprises a threaded coupling means.
- 41. The medication delivery device of claim 37, wherein the cartridge assembly comprises a housing to accommodate the cartridge and wherein the second coupling means comprises a means for axially coupling or uncoupling the needle assembly from the cartridge assembly.
- •42. The medication delivery device of claim 37, wherein the second coupling means comprises a threaded coupling means.
- A medication delivery device comprising:
  - a cartridge assembly comprising:
    - a housing capable of housing a removable cartridge that has a pierceable seal at one end, is filled with medication, and has a moveable stopper at an opposite end that when moved toward the medication pressurizes the medication; and
  - a needle mounting means for mounting a needle on the cartridge assembly;
  - a dosage assembly for delivering a set dose of medication, comprising:

    a plunger means for moving the stopper, a dose setting means for setting
    a dose, and a drive means for driving the plunger means to deliver the
    - set dose, wherein after a portion of medication is expelled from the cartridge, the plunger means abuts the stopper:
  - a first means for coupling and uncoupling a needle assembly to and from the cartridge assembly; and
  - a second means for coupling and uncoupling the dosage assembly to and from the cartridge assembly,

wherein the first and second coupling means are chosen so that when a user simultaneously grasps the dosage assembly and the needle assembly and applies a force to the needle assembly to couple (or uncouple) the needle to or from the device the



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cartridge assembly is positively precluded from moving axially relative to the cartridge assembly;

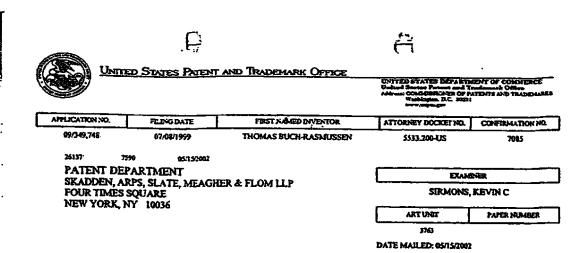
wherein at least the first or second coupling means comprises a snap lock.

#### 44. A medication delivery device comprising:

- a cartridge assembly for housing a removable cartridge containing a medication;
- a needle assembly:
- a dosage assembly comprising a mechanism for setting a dosage less than the full amount of medication contained in the cartridge;
- a first coupling means for coupling and uncoupling the needle to and from a removable cartridge housed in the cartridge assembly; and
- a second coupling means for coupling and uncoupling the cartridge assembly to and from the dosage assembly;

wherein the first coupling means comprises a snap lock; and wherein the first and second coupling means are ischosen so that when a user couples or uncouples the needle assembly from the cartridge by grasping the needle assembly and the dosage assembly simultaneously and applying force to both, the second coupling means prevents axial movement of the cartridge assembly relative to the dosage assembly.





Please find below and/or attached an Office communication concerning this application or proceeding.

<u>,</u>		
	Application No.	Applicant(s)
Notice of Allowability	09/349,748	BUCH RASMUSSEN ET
The state of the s	Examiner	Art Unit
	Kevin C. Sirmons	3763
ut claims being allowable, PROSECUTION ON THE previously mailed), a Notice of Allowable, 10TICE OF ALLOWABILITY IS NOT A GRANT (with the Office or upon petition by the applicant. See 1. This communication is responsive to 1/22/0	HE MERITS IS (OR REMAINS) CLOSI nce (PTOL-85) or other appropriate co OF PATENT RIGHTS. This application 37 CFR 1.313 and MPEP 1308.	rorregation will be malled in the second
2 The allowed claim(s) is/are_1-11.	<u></u>	
1. A The drawings filed on Thomas accepted t	by the Examiner	
<ol> <li>Acknowledgment is made of a claim for fore</li> </ol>	eign priority under 35 U.S.C. § 119(a).	d) or (f).
a) All b) Some c) None		
1.  Certified copies of the priority d	ocuments have been received.	
2. L. Certified copies of the priority d	ocuments have been received in Appli	cation No
3. L. Copies of the certified copies of	the priority documents have been rec	eived in this national stage application fi
International Bureau (PCT R	ule 17.2(a)).	
* Certified copies not received:		•
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i. Acknowledgment is made of a claim for dom	re provisional appecation has been rec	erved.
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upplicant has THREE MONTHS FROM THE "MAIL Mow. Failure to timely comply will result in ABAN	LING DATE* of this communication to DONMENT of this application. THIS	file a reply complying with the requireme THREE-MONTH PERIOD IS NOT EXTE
I. A SUBSTITUTE OATH OR DECLARATION RFORMAL PATENT APPLICATION (PTO-152) W	must be submitted. Note the attached hich gives reason(s) why the oath or d	EXAMINER'S AMENDMENT or NOTIC aclaration is deficient.
L CORRECTED DRAWINGS must be submitted  (a) including changes required by the Notice	e of Draftsperson's Patent Drawing R	eview ( PTO-948) attached
1) hereto or 2) to Paper No		
(b) including changes required by the prop	osed drawing correction filed	which has been approved by the Exami
(c) including changes required by the attac	hed Examiner's Amendment / Comme	nt or in the Office action of Paper No
identifying indicia such as the application number of each sheet. The drawings should be filed as a	r (see 37 CFR 1.84(cj) should be written o separate paper with a transmittal letter a	on the drawings in the top margin (not the ddressed to the Official Draftsperson.
. DEPOSIT OF and/or INFORMATION ab tached Examiner's comment regarding REQUIRE	out the deposit of RIOI OCICAL A	ATEDIAL mount be sub-itted as a su
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Notice of References Cited (PTO-892)	2∏ Notic	ce of Informal Patent Application (PTO-1
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Information Disclosure Statements (PTO-1449) Examiner's Comment Regarding Requirement	), Paper No 6[] Exar	niner's Amendment/Comment
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Application/Control Number: 09/349,748

Art Unit: 3763

#### Page 2

#### DETAILED ACTION

#### Allowable Subject Matter

Claims 34-44 are allowable over the prior art of record at the time the invention was made.

The following is an examiner's statement of reasons for allowance: Claims 34, 37, 43 and 44 are allowable over the prior art of record because the prior art does not disclose or render obvious the combination of a first or second coupling means which comprises a snap lock for assisting in coupling or uncoupling of a needle assembly from a cartridge by grasping the needle assembly and the dosage assembly simultaneously and applying force to both, thus preventing the cartridge assembly from moving axially with respect to the dosage assembly.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Aflowance."

#### Conclusion

Any inquiry concerning this communication or earlier communication from the examiner should be directed to Kevin C. Sirmons whose telephone number is (703) 306-5410. The examiner can normally be reached on Monday - Thursday from 6:30 am to 4:00 pm. The examiner can also be reached on alternate Fridays.

Kevin C. Sirmons Patent Examiner

1/23/03

SUPERVISORY PATENT EXAMINER TECHNOLOGY CENTER 3700





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#### NOTICE OF ALLOWANCE AND FEE(S) DUE

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PATENT DEPARTMENT SKADDEN, ARPS, SLATE, MEAGHER & FLOM LLP FOUR TIMES SQUARE NEW YORK, NY 10036

01/27/2001

EXAMINER
SIRMONS, KEVIN C
AKTUNT CLASS-SINCLASS

DATE MAILED: 01/27/2003

APPLICATION NO. FILING DATE FIRST NAMED DIVENTOR ATTORNEY DOCKET NO. CONFIRMATION NO. 09/349,748 07/08/1999 THOMAS BUCH-RASMUSSEN 5533,200-US 7085

TITLE OF INVENTION: MEDICAL DEVICE

APPLICATIVE SMALL ENTITY ISSUE FEE MUBLICATION FEE TOTAL FEE(S) BUE DATE DUE mongrovisional NO \$1300 \$0 \$1300 04/24/2003

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1398.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE REFLECTS A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE APPLIED IN THIS APPLICATION. THE PTOL-85B (OR AN EQUIVALENT) MUST BE RETURNED WITHIN THIS PERIOD EVEN IF NO FEE IS DUE OR THE APPLICATION WILL BE REGARDED AS ABANDONED.

HOW TO REPLY TO THIS NOTICE:

I. Review the SMALL ENTITY status shown above.

If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

A. If the status is the same, pay the TOTAL FEE(S) DUE shown above,

B. If the status is changed, pay the PUBLICATION FEE (if required) and twice the amount of the ISSUE FEE shown above and notify the United States Patent and Trademark Office of the change in status, or

If the SMALL ENTITY is shown as NO:

A. Pay TOTAL FEE(S) DUE shown above, or

B. If applicant claimed SMALL ENTITY status before, or is now claiming SMALL ENTITY status, check the box below and enclose the PUBLICATION FEE and 1/2 the ISSUE FEE shown above.

□ Applicant claims SMALL ENTITY status. See 37 CFR 1.27.

II. PART B - FEE(S) TRANSMITTAL should be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). Even if the fee(s) have already been paid, Part B - Fee(s) Transmittal should be completed and returned. If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Box ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

Page 1 of 4

FTOL-85 (REV. 04-02) Approved for use through 01/31/2004.

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#### United States Patent and Trademark Office

United States Department of Cosmerce United States Potent and Trestment Office Address Councilington of Patients and Tradenaktic Vantages, D.C. 2021

APPLICATION NO.	FILING DATE	FIRST NAMED ENVENTOR	ATTORNEY DOCKET NO.	CONFERMATION NO.
09/349,748	07/9 <b>8</b> :1999	THOMAS BUCH-RASMUSSEN	5533.200-US	7085
26137	7590 01/27/2003		EKAMIN	ER
PATENT DEF	ARTMENT	- + TI OVI I I	SIRMONS, N	EVIN C
FOUR TIMES	IPS, SLATE, MEAGHEI SOUARE	K & PLUM LLP	art unit	PAPER NUMBER
NEW YORK, N	TY 10036		3763	
UNITED STAT	EZ		DATE MAILED: 01/27/2003	

## Determination of Patent Term Extension under 35 U.S.C. 154 (b) (application filed after June 7, 1995 but prior to May 29, 2000)

The patent term extension is 0 days. Any patent to issue from the above identified application will include an indication of the 0 day extension on the front page.

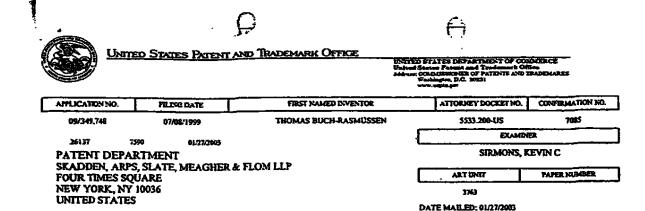
If a continued prosecution application (CPA) was filed in the above-identified application, the filing date that determines patent term extension is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) system. (http://pair.uspto.gov)

Any questions regarding the patent term extension or adjustment determination should be directed to the Office of Patent Legal Administration at (703)305-1383.

Page 3 of 4

PTOL-85 (REV. 04-02) Approved for use through 01/31/2004.



#### Notice of Fee Increase on January 1, 2003

If a reply to a "Notice of Allowance and Fee(s) Due" is filed in the Office on or after January 1, 2003, then the amount due will be higher than that set forth in the "Notice of Allowance and Fee(s) Due" since there will be an increase in fees effective on January 1, 2003. <u>See Revision of Patent and Trademark Fees for Fiscal Year 2003</u>; Final Rule, 67 Fed. Reg. 70847, 70849 (November 27, 2002).

The current fee schedule is accessible from: http://www.usoto.gov/main/howtofees.htm.

If the issue fee paid is the amount shown on the "Notice of Allowance and Fee(s) Due," but not the correct amount in view of the fee increase, a "Notice to Pay Balance of Issue Fee" will be mailed to applicant. In order to avoid processing delays associated with mailing of a "Notice to Pay Balance of Issue Fee," if the response to the Notice of Allowance and Fee(s) due form is to be filted on or after January 1, 2003 (or mailed with a certificate of mailing on or after January 1, 2003), the issue fee paid should be the fee that is required at the time the fee is paid. If the issue fee was previously paid, and the response to the "Notice of Allowance and Fee(s) Due" includes a request to apply a previously-paid issue fee to the issue fee now due, then the difference between the issue fee amount at the time the response is filed and the previously paid issue fee should be paid. See Manual of Patent Examining Procedure, Section 1308.01 (Eighth Edition, August 2001).

Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at (703) 305-8283.

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PTOL-85 (REV. 04-02) Approved for use through 01/31/2004.

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Attorney Ducket No.: 5533,200-US

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Certificate

of Correction

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In re Application of: Buch-Rasmussen et al.

Group Art Unit: 3763

Script No.: 09/349\_748 Filed: July 8, 1999

Exeminer: K. Sirmons

For: Medical Device

Patent No.: 6,582,408

issued: June 24, 2003

FACSIMILE CERTIFICATE OF TRANSMISSION Via Facsimile No.: 571-273-8300

Certificates of Correction Branch Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir.

I hereby certify that the attached correspondence comprising:

1. Request for Certificate of Correction of Patent for Applicant's Mistake (in duplicate)

2. Form PTO/SB/44 (also Form PTO-1050)

is being deposited with the United States Patent and Trademark Office via facsimile so. 571-273-8300 on August 9, 2005.

Rashida Hoji

(name of person mailing paper)

PAGE 118 \* RCVD AT 889(2005 3:16:16 PM [Eastern Daylight Time] \* SVR:USPTO-EFXRF-6/31 \* DNIS:2738300 \* CSID:6099873995 \* DURATION (mm-ss):01-38

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Parent No. 6.582,406, issued Jun. 24, 2003 Attorney Docket No.; 5533,200-US Vin Facsimile No.; 571-273-\$300 5533,200-US RECEIVED CENTRAL FAX CENTER

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## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Patent No:

6,582,408

issued:

June 24, 2003

Name of Patentee:

Buch-Rasmussen et al.

Title of invention:

Medical Device

Serial No.: Examiner: 09/349.748 Kevin C. Sirmons

Certificates of Correction Branch Commissioner for Patents P. O. Box 1450 Alexandria, VA 22313-1450

# REQUEST FOR CERTIFICATE OF CORRECTION OF PATENT FOR APPLICANT'S MISTAKE [37 C.F.R. §1.323]

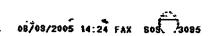
- Patentees request correction of two errors in the above-referenced patent by issuance of a Certificate of Correction.
- 2. The first error appears in claim 1, col. 6, line 23. The text "cannot not move" (incorrect) should read "cannot move" (correct).
- 3. The second error appears in claim 10, col. 8, lines 5-7. The text "the cartridge assembly is positively precluded from moving axially relative to the cartridge assembly" (incorrect) should read "the cartridge assembly is positively precluded from moving axially relative to the desage assembly" (correct).
- 4. Support for both of these corrections is found in the application as originally filed at page 4. lines 21-26; and in the issued patent at col. 3, lines 15-22;

"In particular, when the cartridge assembly is released from the dosing assembly through a movement including an axial movement, such as through a threaded coupling, it is preferred that the means for releasably coupling the needle

AGE 298 \* RCYD AT 87972005 3:16:16 PM [Eastern Daylight Time] \* SYR:USPTO-EFXRF-6/31 \* DMS:2/730300 \* CSD:60998/7395 \* DURATION (mm-ss):01-38

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Patent No. 6,582,408, issued Jun. 24, 2003 Attorney Docket No.: \$533,200-US Via Pacsimile No.: 571-273-8300 Page 2 of 3

> assembly and the cartridge assembly together are such that the coupling and/or decoupling of the needle assembly cannot cause an axial movement of the cartridge assembly with respect to the dosing assembly."

The correct information also appears in the prosecution history in the Amendment dated August 15, 2002, at page 7, first full paragraph: "[T]he means for securing the dosing assembly to the curtridge assembly must prevent unintended axial movement of the dosage assembly relative to the contridge assembly."

- In each instance, the mistake is of a clerical nature, of minor character and self-5. evident. In view of the support in the application as filed, as well as the clear purport of the claim language, the requested corrections would not involve new matter, nor would they require reexamination of the application.
- Attached is a copy of Form PTO/SB/44 (also Form PTO-1050), specifying a correction to 6. each of the errors.
- Please authorize and issue the Certificate of Correction to the undersigned Attorney. 7.

Patentees attach copies of the relevant pages from the prosecution history.

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Patent No. 6,532,408, issued Jun. 24, 2003 Attorney Docket No.: 5533:200-US Via Facsimile No.: 571-273-8300 Page 3 of 3

The Commissioner is authorized to charge the fee for this Petition for Certificate of 8: Correction per 37 C.F.R. §1.20(a), and any additional fees which may be due, to Deposit Account No.14-1447.

Dated: August 9, 2005

Respectfully submitted,

Marc A. Began Reg. No. 48,829 Customer No. 23650 Novo Nordisk 100 College Road West Princeton, NJ 08540

Direct Line: (609) 919-7829

**Enclosures** 

PAGE 48 "RCVD AT 8/92015 3:14:16 PM (Eastern Dayligh Time)" SVR:USPTO-EFXBF-6/31 "DNBS:2/738300" CSID:5099873095" DURATION (pag-ss):01:38

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Patem No. 6,582,408, issued Jun. 24, 2003 Attorney Docket No.: 5533 200-US Via Facsimile No.: 571-273-8300

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## PATENT

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Patent No:

6,582,408

Issued:

June 24, 2003

Name of Patentee:

Buch-Rasmussen et al.

Title of Invention: Serial No.:

Medical Device 09/349,748

Examiner:

Kevin C. Sinnons

Certificates of Correction Branch Commissioner for Patents P. O. Box 1450 Alexandria, VA 22313-1450

#### REQUEST FOR CERTIFICATE OF CORRECTION OF PATENT FOR APPLICANT'S MISTAKE [37 C.F.R. §1.323]

- Patentees request correction of two errors in the above-referenced patent by issuance of a Certificate of Correction.
- The first error appears in claim 1, col. 6, line 23. The text "cannot not move" (incorrect) should read "cannot move" (correct).
- The second error appears in claim 10, col, 8, lines 5-7. The text "the eartridge assembly is positively precluded from moving axially relative to the cartridge assembly" (incorrect) should read "the cartridge assembly is positively precluded from moving axially relative to the desage assembly" (correct).
- Support for both of these corrections is found in the application as originally filed at page 4, lines 21-26; and in the issued patent at col. 3, lines 15-22;

"In particular, when the cartridge assembly is released from the dosing assembly through a movement including an axial movement, such as through a threaded coupling, it is preferred that the means for releasably coupling the needle

PACE 58 \* RCVD AT 819/2005 3:16:16 PM (Eastern Dayligh) Time] \* SVR:USPTO-EFXRF-6/31 \* DNRS:2738300 \* CSD:6099873095 \* DURATION (mm-ss):01-38

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Potent No. 6.582,408, issued Jun. 24, 2003 Attorney Docket No.: 5533,2004-US Vin Factimite No.: 571-273-8300 Page 2 of 3

assembly and the cartridge assembly together are such that the coupling and/or decoupling of the needle assembly cannot cause an axial movement of the cartridge assembly with respect to the dusing assembly."

The correct information also appears in the prosecution history in the Amendment dated August 15, 2002, at page 7, first full paragraph: "[T]he means for securing the dosing assembly to the cartridge assembly must prevent unintended axial movement of the dosage assembly relative to the cartridge assembly."

- 5. In each instance, the mistake is of a clerical nature, of minor character and selfevident. In view of the support in the application as filed, as well as the clear purport of the claim language, the requested corrections would not involve new matter, nor would they require reexamination of the application.
- 6. Attached is a copy of Form PTO/SB/44 (also Form PTO-1050), specifying a correction to each of the errors.
- 7. Please authorize and issue the Certificate of Correction to the undersigned Attorney.

Patentees attach copies of the relevant pages from the prosecution history.

ATTEMENT OF THE PROPERTY OF THE PERSONS

-2-

PAGE 58 "RCVD AT 89/7005 1:16:16 PM [Eastern Daylight Time] "SYR-USP TO EFXIF-6/31" DMS-1732300" CSD-6/099173005" DURATION (mm-ss):01-38

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Patent, No. 6,582,408, issued Jun. 24, 2003 Attorney Docket No.: 5533-200-115 Via Facsimile No.: 571-273-8300 Page 3 of 3

The Commissioner is authorized to charge the fee for this Petition for Certificate of Correction per 37 C.F.R. §1.20(a), and any additional fees which may be due, to Deposit Account No.14-1447.

Dated: August 9, 2005

**Enclosures** 

Respectfully submitted.

Marc A. Begun Reg. No. 48,829 Customer No. 23650 Novo Nordisk

100 College Road West Princeton, NJ 08540

Direct Line: (609) 919-7829

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PATENT

#### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Patent No:

6.582.408

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June 24, 2003

Name of Patentee: Title of Invention: Buch-Rasmussen et al.

Serial No.:

Medical Device

Serial No.: Examiner: 09/349.748 Kevin C. Sirmons

Certificates of Correction Branch Commissioner for Patents P. O. Box 1450 Alexandria, VA 22313-1450

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- 4. Support for both of these corrections is found in the application as originally filed at page 4, lines 21-26; and in the issued patent at col. 3, lines 15-22:

"in particular, when the cartridge assembly is released from the dosing assembly through a movement including an axial movement, such as through a threaded coupling, it is preferred that the means for releasably coupling the needle

PAGE 271 \* RCVD AT 8/97895 1:14:16 PM (Eastern Daylight Time) \* SVR:USPTO-EFXRF-6731 \* DHS:2738360 \* CSID:5099873195 \* DURATION (pag-55):11:38

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## UNITED STATES PATENT AND TRADEMARK OFFICE CERTIFICATE OF CORRECTION

Patent No:

6,582,408 B\ June 24, 2003

Issued:

Name of Patentee: Buch-Rasmussen et al.

Page 1 of 1

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below;

Col. 6

Line 23: "cannot not move" should read "cannot move".

Col 8

Line 7: "cartridge assembly" should read "dosage assembly".

MAILWIGAULINESS OF SENDER.

Marc A. Began, Esq. Novo Nordisk, Inc.

100 College Road, West

Princeton, NJ 08540

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(Cenificae of Correction (PTO/St/44) [14-3]-- page 1 of 1)

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(Also Form PTO-1850)

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# UNITED STATES PATENT AND TRADEMARK OFFICE CERTIFICATE OF CORRECTION

Patent No: Issued: Name of Patentee: 6,582,408 (5) June 24, 2003

Buch-Rasmusson et al.

Page 1 of 1

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

Cal. 6

Line 23: "cannot not move" should read "cannot move".

Col. 8

Line 7: "cartridge assembly" should rend "dosage assembly".

MARING ACHINESS OF SENDER

Marc A. Began, Esq. Novo Nordisk, Inc. 100 College Road, West

Princeton, NJ 08540

butter Hour Statement, This form to extended to take 1.0 hour to complete. Time will vary deplanding upon the needs of the Individual case, Any comments on the arroyal of firm you are required to complete this form should be sent to the Crool information Officer, Peneru and Trademate Office, Washington, DC 20231, DO NOT SEND FEES OR COMPLETED FORMS TO THAS AUDITEST. SEND TO: Assistant Commission to Patents, Washington, DC 20231

(Certificate of Correction (PTC/SB/44) [14-3]- page 1 of 1)

PAGE 819 'RCVD AT \$197005 1:16:16 PM Eastern Daylight Time] 'SVR:USPTO EFXRF-6131 'DHIS:2730300' CSD:5099873095' DURATION from-sst 01:38

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### UNITED STATES PATENT AND TRADEMARK OFFICE CERTIFICATE OF CORRECTION

PATENT NO. : 6,582,408 B1 DATED

: June 24, 2003

Page 1 of 1

INVENTOR(S) : Buch-Rasmussen et al.

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

Cohuma 6.

Line 23, "cannot not move" should read - cannot move -.

Column 8.

Line 7, "cartridge assembly" should read - dosage assembly -.

Signed and Sealed this

Thirteenth Day of September, 2005

JON W. DUDAS Director of the United States Patent and Trademark Office Ŀ

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# Arcachment for PTO-948 (Rev. 03/01, or carlier) 6/18/01

The below text replaces the pre-printed text under the heading, "Information on How to Effect Drawing Changes," on the back of the PTO-948 (Rev. 03/01, or earlier) form.

## INFORMATION ON HOW TO EFFECT DRAWING CHANGES

#### I. Correction of Informalities -- 37 CFR 1.85

New corrected drawings must be filled with the changes incorporated therein Identifying indicia, if provided, should include the rule of the invention inventor's name, and application number, or docket number (if any) if an application number has not been assigned to the application. If this information is provided, it must be placed on the front of each sheet and centered within the top margin. If corrected drawings are required in a Notice of Allowability (PTOL-37), the new drawings MIIST be filled within the THREE MONTH shortened statutory period set for reply in the Notice of Allowability. Extensions of time may NOT be obtained under the provisions of 37 CFR 1 136(a) or (b) for filling the corrected drawings after the mailing of a Notice of Allowability. The drawings should be filed as a separate paper with a transmittal letter addressed to the Official Draftsperson.

2. Corrections other than informalities Noted by Braftsperson on form PTO-948.

All changes to the drawings, other than informalities noted by the Draftsperson, MUST be made in the same manner as above except that, normally, a highlighted (preferably red ink) sketch of the changes to be incorporated into the new drawings MUST be approved by the examiner before the application will be allowed. No changes will be permitted to be made other than correction of informalities, unless the examiner has approved the proposed changes.

#### Timing of Corrections

Applicant is required to submit the drawing corrections within the time period set in the attached Office communication See 37 CFR 1.85(a)

Failure to take corrective action within the set period will result in ABANDONMENT of the application.

## Attachment for PTO-948 (Rev. 03/01. or carlier)

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## ATTACHMENT TO AND MODIFICATION OF **NOTICE OF ALLOWABILITY (PTO-37** (November, 2000)

NO EXTENSIONS OF TIME ARE PERMITTED TO FILE CORRECTED OR FORMAL DRAWINGS, OR A SUBSTITUTE OATH OR DECLARATION, notwithstanding any indication to the contrary in the attached Notice of Allowability (PTO-37):

If the following language appears on the attached blotice of Allowability, the nonton ined through below is of no force and effect and tare be unused.

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### **Timing of Corrections**

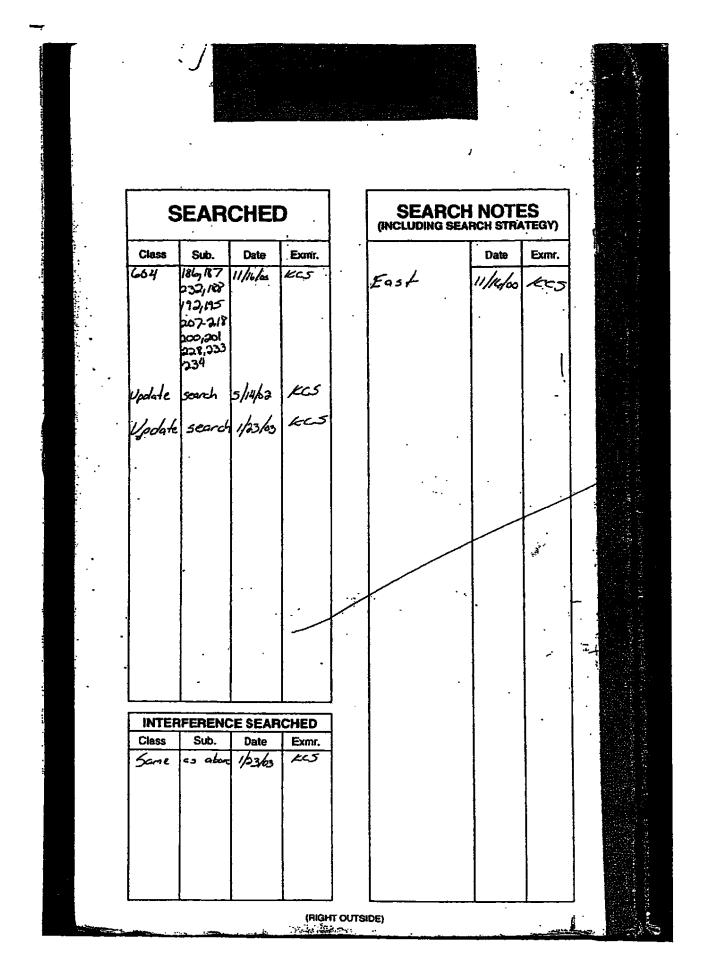
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Failure to take corrective action within the set period will result in ABANDONMENT of the application.

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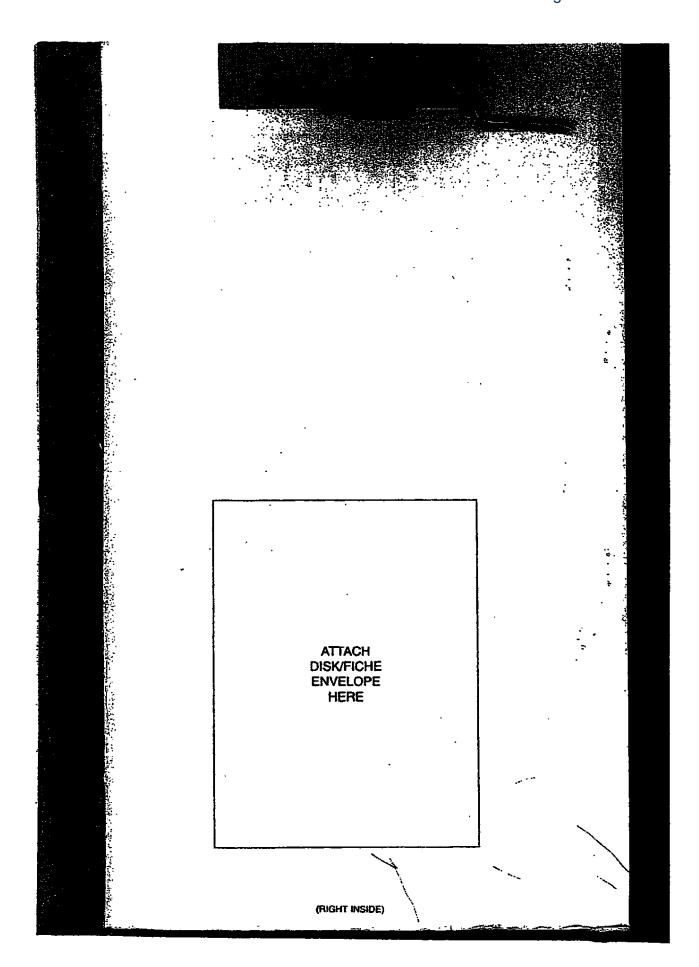
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# EXHIBIT 3



## Kongeriget Danmark

# PRIORITY DOCUMENT

Patent application No.: PA

PA 1998 00910

Date of filing:

08 July 1998

Applicant:

Novo Nordisk A/S

Novo Allé

DK-2880 Bagsværd

This is to certify the correctness of the following information:

The attached photocopy is a true copy of the following document:

The specification, claims and drawings as filed with the application on the filing date indicated above.





Patent- og Varemærkestyrelsen Erhvervsministeriet

TAASTRUP 26 November 1999

Karin Schlichting Head Clerk 28/27/98

13:14

HEIDEN & HOIBERG → 43508201

NR.571

Modtaget PD - 8 JULI 1998

P 227 DK

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The present invention relates to a medication delivery device having a cartridge assembly and a dosing assembly coupled together for delivering selected doses of medication.

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#### Background

Some medication, such as Insulin is self-administered. The typical diabetes patient will require injections of insulin several times during the day. The required insulin dose will vary from patient to patient, and will for each patient often also vary during the day. Each patient will often establish a regimen for the insulin administration adjusted to his or her insulin need as well as lifestyle. Medication delivery pans have been developed to facilitate the self-administration of medication, such as insulin.

15 One prior art medication delivery pen includes a pan body assembly comprising a medication cartridge and a plunger device. A needle assembly may be connected to the pen body assembly. The medication is delivered by moving or pressing a plunger in the direction of the needle assembly thereby delivering the medication. When the medication in the cartridge is exhausted the pen body assembly is dis-20 carded. Depending on the medication needs for each individual the medication in the cartridge will last for several days. During this period the needle assembly will often have to be displaced by a new assembly or new needle due to increasing biuntness of the needle making injections painful for the patient.

25 Due to the environmental and economical reasons medication delivery pens were developed, for which pens only a part of the pen was discarded after medication exhaustion, such as the cartridge only.

An example of prior art pens is disclosed in EP 0 688 571 wherein a medication delivery pen has a reusable pen body assembly and a disposable cartridge assembly that are threadedly engageable with one another. The disposable cartridge assembly includes a plunger and can releasably receive a needle cannula assembly through a threaded coupling. A driving means in the pen body assembly engages the plunger after engagement of the pen body assembly and the cartridge assembly. whereby the pen is ready for dosing the medicine within the cartridge. The cartridge

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holder assembly can be disassembled from the pen body assembly after the medication therein has been exhausted, discarded and replaced.

However, a drawback of the above-mentioned pen is that the driving means of the pen body may be disengaged from the plunger of the cartridge during normal use resulting in inaccurate dosing of the medicine.

For the device disclosed in EP 0 688 571, the needle assembly will often have to be replaced independently of replacement of the cartridge. When releasing the needle assembly from the cartridge assembly the cartridge assembly may inadvertently be released or partly released from the pen body assembly. Thereby the driving means of the pen body may be disengaged from the plunger of the certridge. In particular if the pen body assembly is only partly released from the cannidge assembly the user will most probably not be aware of the disengagement but will receive only a portion or even nothing of the medicine.

Even pens with differently pitched threaded couplings and/or threaded couplings having different diameters whereby the force exerted to fasten and/or release one coupling is greater than the force necessary for the other coupling present this problem. It is easy to imagine that a small obstruction (a sandskom, for example) to the emoothest going coupling will necessitate a greater force to faster/release that coupling which force tends towards the force necessary for the other coupling.

Accordingly, it is an object of the present invention to provide a medication delivery device with which the inadvertent disengagement of the driving means and plunger means from the plunger or stopper in the cartridge is avoided.

#### Summary of the invention

According to a first aspect of the invention a medication delivery device is provided which comprises

a cartridge assembly, having one end sealed with a plerceable sealing, said end of the cartridge assembly comprising coupling means for releasably mounting a needle 08/27/99

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assembly, and comprising a cartridge having a stopper adapted to receive plunger means,

a dosing assembly comprising plunger means,

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and optionally a needle assembly,

wherein the cartridge assembly and the dosing assembly are coupled together, and the device further comprises means for securing that the plunger means abuts on the stopper during use of the device

in a preferred embodiment the dosing assembly is reusable and the cartridge assembly is disposable, and accordingly, a second aspect of the present invention is a medication delivery device wherein the dusing assembly is releasably coupled to the cartridge assembly.

By the term "use of the device" is meant the normal use, including measuring and delivering the medication, removing a cap from the cartridge assembly and/or needia as well as attaching and releasing the needle assembly. It is understood that the plunger means must disengage the slopper when the cartridge assembly is deliberately released from the dosing assembly because the medication in the cartridge has been exhausted and the cartridge assembly is to be discarded. In this situation the plunger means is to be retracted to the dosing assembly before assembling the device with a new cartridge assembly.

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Securing the abutment of the plunger means on the stopper during use of the medication delivery device, in particular when the needle assembly is coupled to and/or decoupled from the cantridge assembly, may be carried out by a variety of means. In a preferred embodiment the abulment is secured by preventing the cartridge assembly from being inadvertently released from the dosing assembly.

Furthermore, it is a preferred aspect of the invention to provide a medication delivery device, which device is arranged for securing that the plunger means abute on the stopper during coupling and/or decoupling of the needle assembly.

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In one embodiment of the invention the dosing assembly is coupled to the cartridge assembly at the end of the cartridge assembly opposite the means for mounting the needle assembly, and the plunger means is a rod element adapted to exert an exial movement of the stopper lowerds the sealed end of the cartridge.

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Accordingly, it is an aspect of the present invention to provide a medication delivery device, wherein the means for coupling the dosing assembly and the cartridge assembly together are such that the coupling and/or decoupling of the needle assembly does not cause an axial movement of the cartridge assembly with respect to the dosing assembly. In this way it is assured that the rod element does not disengage the slopper in the cartridge when the user attaches the needle assembly or removes it after use. Thereby the user can be confident of the accuracy of the dosage selected.

The means for coupling the dosing assembly and the cartridge assembly together may be any suitable coupling, preferably a releasable coupling. Examples of the coupling are snap locks, such as snap locks with guidewire and sideways snap locks, snap locks released through threads, bajonet locks, luer locks, hinged locks,

threaded locks and any suitable combinations thereof.

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In particular, when the cartridge assembly is released from the dozing assembly through a movement including an axial movement, such as through a threaded coupling, it is preferred that the means for releasably coupling the needle assembly and the cartridge assembly together are such that the coupling and/or decoupling of the needle assembly cannot cause an axial movement of the certridge assembly with respect to the dosing assembly. Thus, in that respect examples of the preferred couplings between the needle assembly and the cartridge assembly include releasable snap locks. Another preferred embodiment includes a safety on the coupling between the dosing assembly and the cartridge assembly, such as hinge on the coupling or a threaded coupling releasable only after exerting an axial pressure on the coupling.

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According to the invention preferred combinations of couplings between the dusing assembly and the cartridge assembly and between the needle assembly and the cartridge assembly, respectively, are a threaded coupling combined with a snap

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coupling, a bajonal lock or a luer tock combined with a snap lock, or a snap lock combined with a snap lock, or any other combination for which the couplings are independently working.

Another aspect of the present invention is a cartridge assembly for use in the medication delivery device according to the invention. The cartridge assembly comprises a cartridge for the medication to be delivered. The cartridge assembly has one end shalled with a pierceable scaling, said end of the cartridge assembly comprising coupling means for releasable mounting a needle assembly, and enother end comprising coupling means adapted to engage a dosing assembly. Furthermore, the cartridge comprises a stopper.

The cartridge assembly may further comprise a housing for protecting at least a part of the cartridge assembly.

In a preferred embodiment at least one of the coupling means of the cartridge assembly is unitarily moulded with the cartridge, and in a more preferred embodiment all the coupling means are unitarily moulded with the cartridge. In the letter case the cartridge assembly may be comprised of just one part, i.e. the cartridge including the coupling means.

#### Drawings

Fig. 1 is an exploded perspective view of the medication delivery device.

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Fig 2 is a cross-sectional view showing part of the medication delivery device, 2a immediately after assembling before the first injection, and 2b after some time of time.

30 Fig 3 is a cross-sectional view showing the cartridge before assembling of the medication delivery device. 08/87/98 13:14 HEIDEN & HOIDERG + 43508001

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#### Detailed description of the Invention

A medication delivery device in accordance with the present invention is identified generally by the numeral 20 in Fig. 1 and 2 Medication delivery device 20 includes a dosing assembly 6, and carbridge assembly 1, a needle assembly 16 and a cap

The dosing assembly 6 is illustrated in Fig. 1 and 2. It is understood, however, that the dosing assembly 6 according to the invention may be any suitable dosing unit including plunger means, and accordingly, that variations from the depicted embodiment may be provided, and are considered to be within the scope of this invention. In the depicted embodiment the dosing assembly 6 includes a cylindrical housing surrounding the plunger means 17 of the dosing unit and having opposed proximal and distal ends.

In one aspect of the invention the plunger means comprises a rod element 7 which is adapted to engage the stopper 4 of the cartridge assembly 1. The rod element 7 advances axisity into the cartridge 5 during injections. The dosing assembly may have any suitable driving means for advancing the rod element 7.

The desing unit 6 preferably also comprises scale means 10 indicating the desing quantity selected by activating the dose setting means 9 for defining specified selected doses of medication to be delivered. The selected dose may be delivered by actuating the actuator button 18. The actuator button is part of the driving means of the dosing assembly exerting its force on the rod element 7.

The dosing assembly further comprises coupling means 8 adapted for engagement with the cartridge assembly. The coupling means 8 may be internal or external couplings in a preferred embodiment the coupling 8 is an internal coupling.

The cartridge assembly 1 is illustrated in Fig. 1 and 2, and in greater detail in Fig. 3, in Fig. 1 cartridge assembly 1 includes a moulded certridge 5 extending from proximal end 21 to distal and 22.

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At the distal end 22 of the cartridge assembly 1 is provided coupling means 2 for releasably mounting a needle assembly 11. At the proximal end 21 of the cartridge assembly 1 is provided coupling means 3 for mounting a dosing assembly 6. The coupling means are as described above

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Cartridge 5 also comprises a slopper 4 in sliding fluid tight engagement within said cartridge 5. The stopper 4 is adapted to receive the plunger means, such as a rod element 7 of the dosing assembly 6.

10 The cartridge assembly 1 may further comprise a housing for protecting some or all of the cartridge 5. When the cartridge assembly 1 includes a housing, one or both of the couplings 2, 3 of the cartridge may be moulded unitarily with the housing.

in a preferred embodiment at least one of the couplings 2, 3 is moulded unitarily with 15 the carridge 5, minimising the total number of parts of the device and thereby the production costs

Instead of the protective housing the cartridge 5 may have integrally moulded reinforcements of the certridge wall.

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The depicted cartridge 5 is cylindrical having couplings 2, 3 at opposed ends. However, the cartridge may obtain any suitable form and the cross-section may be circular or non-circular, such as substantially triangular or oval.

- 25 In Fig. 1 and Fig. 2 the couplings 2, 3 are opposing each other. However, coupling 2 being separate from coupling 3 may be arranged in any angle with respect to coupling 3.
- A suitable choice of material allows the cartridge to be at least partly transparent, 30 whereby the user can see whether liquid is left in the cartridge.

Referring to Fig. 3 the coupling means of the cartridge are shown in greater detail. The coupling means 3 is an external thread, whereas the coupling means 2 is a recess for a snap lock of the needle assembly. Both coupling means are moulded

unitarily with the cartridge. 35

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The device according to the invention may include a protective cap 14 that is removably mounted over the cartridge assembly 1 and/or the needle 11 and which is removed before injection of the medication in the cartridge 5. The cap further ensures that the content of the cartridge is protected against sunlight.

The various parts of the medication delivery device are advantageously made of plastics, e.g. by injection moulding.

The medication delivery device 20 may further comprise any appropriate needle assembly 11, such as a double ended needle 13 having opposed proximal and distal points and a lumen extending axialty therebetween.

A mounting hub 12 is engaged on the needle 13 and is removably connected to the coupling means 2 at the needle end of the cartridge assembly. The relative location of the mounting hub 12 ensures that the proximal point of the needle 13 will pierce the sealing when the mounting hub 12 is engaged with the coupling means 2 on the cartridge assembly 1.

20 The needle assembly 11 may further comprise a removable shield or cap 15 for protecting against accidental needle sticks.

The device according to the invention is suitable for delivering pre-set dosages of insulin, it is however understood that the device is suitable for the injection of pre-set dosages of other liquids.

In use the user will set the dose by means of the dose setting means 9. Before activating the actuator button 18 the cap 14 must be removed from the cartridge assembly 1 whereby the device 20 is prepared for an injection. The injection is effected by activating the actuator button 18, which again will effect the stopper 4 to be moved towards the needle at the sealed and 22 of the cartridge 5, thereby delivering the desired pre-set dosage. A subsequent dosage of medication will be set in exactly the same manner as described above. However, for such a subsequent dosage, the rod element 7 and the stopper 4 will be in a partly advanced position as

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starting point. Dose setting and injections can be carried out until all of the medication has been used.

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#### Claims:

- 1. A medication delivery device comprising
- a cartridge assembly, having one end sealed with a plerceable sealing, said end of the cartridge assembly comprising coupling means for releasably mounting a needle assembly, and comprising a cartridge having a stopper adapted to receive plunger means,
- 10 a dosing assembly comprising plunger means,

and optionally a needle assembly,

- wherein the cartridge assembly and the dosing assembly are coupled together,

  and the device further comprises means for securing that the plunger means
  abuts on the slopper during use of the device.
  - A medication delivery device according to claim 1, wherein the dosing assembly is releasably coupled to the cartridge assembly.

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- A medication delivery device according to any of the preceding claims, wherein
  the device is arranged for securing that the plunger means abuts on the stopper
  during coupling and/or decoupling of the needle assembly.
- 4. A medication delivery device according to any of the preceding claims, wherein the plunger means comprises a rod element adapted to exert an axial movement of the stopper towards the sealed end of the cartridge.
  - 5. A medication delivery device according to any of the preceding claims, wherein the means for releasably coupling the dosing assembly and the cartridge assembly together are such that the coupling and/or decoupling of the needle assembly does not cause an axial movement of the cartridge assembly with respect to the dosing assembly.

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HEIDEN & HOIBERG + 43588801 NR.571 98/07/98 13:14 11 6. A medication delivery device according to any of the preceding claims, wherein the dosing assembly is released from the cartridge assembly through a movement including an extal movement. 7. A medication delivery device according to claim 6, wherein the dosing assembly 5 is released from the cartridge assembly through a threaded coupling. 8. A medication delivery device according to any of the preceding claims, wherein the dosing assembly comprises scale means. 10 9. A medication delivery device according to any of the preceding claims, wherein the dosing assembly comprises dose setting means for defining specified selected doses of medication to be delivered 10. A medication delivery device according to any of the preceding claims, wherein 15 the cartridge assembly comprises a housing. 11. A medication delivery device according to any of the preceding claims, wherein the cartridge is unitarily moulded with at least one coupling means. 20 12. A medication delivery device according to any of the preceding claims, further comprising a cap for protecting the needle assembly and/or the cartridge assembly. 25 13. A cartridge assembly for use in the medication delivery device as claimed in any of claims 1-12, having one and sealed with a pierceable sealing, said and of the cartridge assembly comprising coupling means for engaging a needle assembly, and another end comprising coupling means adapted to engage a dosing assambly, further comprising a cartridge said cartridge comprising a slidable stop-30 per 14. A cartridge assembly according to claim 13, further comprising a housing.

tarily moulded with at least one coupling means.

15. A cartridge assembly according to claim 13 or 14, wherein the certridge is uni-

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- 18. A certridge assembly according to any of claims 13-15, wherein the coupling means adapted to engage the dosing unit is such that coupling and/or decoupling of the needle assembly does not cause an axial movement of the cartridge essembly with respect to the dosing assembly.
- 17. A cartridge assembly according to any of claims 13-16, wherein the dosing assembly is released from the cartridge assembly through a movement including an axial movement
- 15. A cartridge assembly according to claim 17, wherein the dosing assembly is released from the cartridge assembly through a threaded coupling.

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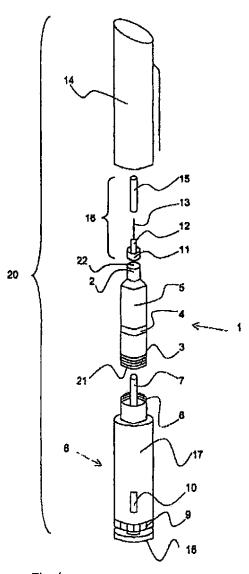
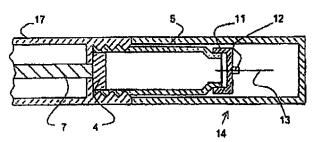


Fig. 1



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Flg. 2 a

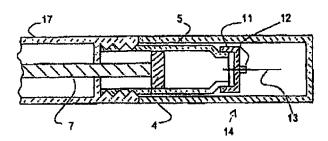
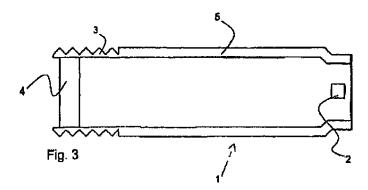
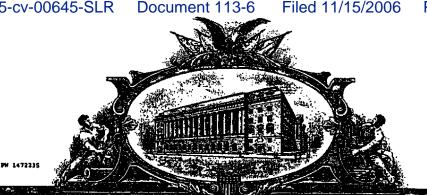


Fig. 2 b



# **EXHIBIT 4**



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June 28, 2006

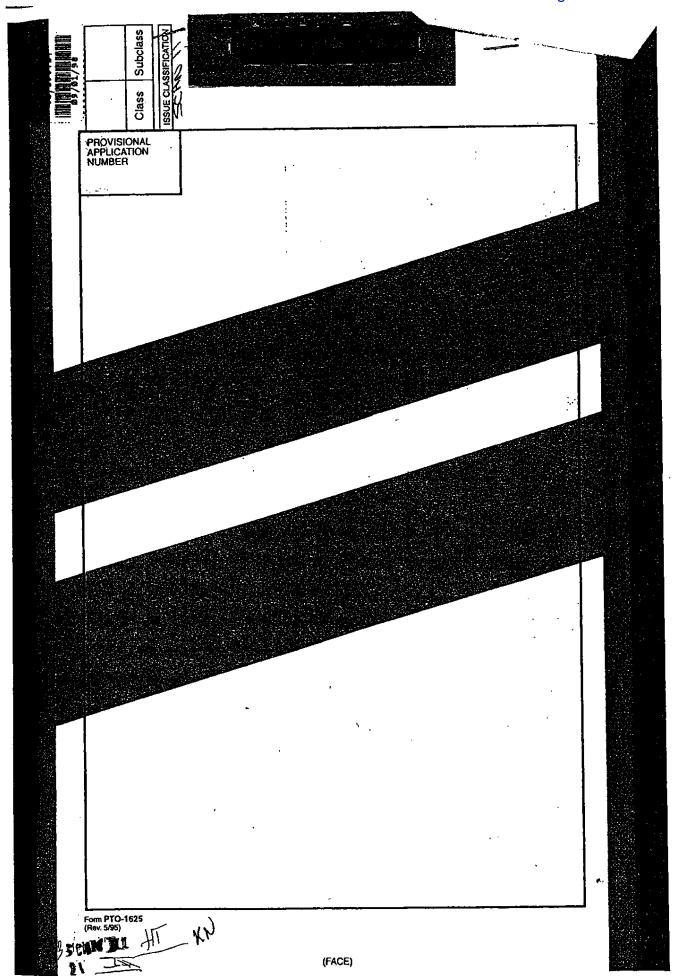
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APPLICATION NUMBER: 60/098,707 FILING DATE: September 01, 1998

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**Certifying Officer** 



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Attorney Docket No.: 5533.003-US

PATENT

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

#### EXPRESS MAIL CERTIFICATE

Assistant Commissioner for Patents Washington, DC 20231

Re: U.S. Provisional Application for

"Medical Device"

Applicants: Buch-Rasmussen.et al.

Sir:

Express Mail Label No. <u>EL021372400US</u>

Date of Deposit September 1, 1998

I hereby certify that the following attached paper(s) or fee

- 1. Filing Under 37 C.F.R. §1.53(c) (in duplicate)
- 2. Provisional Application

are being deposited with the United States Postal Service "Express Mail Post Office to Addressee" under 37 C.F.R. 1.10 on the date indicated above and is addressed to the Commissioner of Patents and Trademarks, Washington, DC 20231.

Gina Maldonado

(Name of person mailing paper(s) or fee)

Signature of person mailing paper(s) or fee)

Mailing Address:

Novo Nordisk of North America, Inc. 405 Lexington Avenue, Suite 6400 New York, NY 10017 (212) 867-0123

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Attorney Docket No.: 5533.003-US

**PATENT** 

#### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

#### FILING UNDER 37 C.F.R. §1.53(c)

Assistant Commissioner for Patents Washington, DC 20231

Express Mail Label No. EL021372400US Date of Deposit September 1, 1998

Sir:

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מה דומים " אמ לפיםם

This is a request for filing a provisional application under 37 C.F.R. §1.53(c), of the inventors:

Buch-Rasmussen, Thomas, a citizen of Denmark, residing at Dalvej 28, DK-2820 Gentofte, Denmark;

Munk, Benny, a citizen of Denmark, residing at Bæverskov Allè 52, DK-2720 Vanløse, Denmark;

Poulsen, Jens-Ulrik, a citizen of Denmark, residing at Virumgade 54 C, DK-2830 Virum, Denmark;

Ljungreen, Henrik, a citizen of Denmark, residing at Jonstrupvej 244 A, DK-2750 Ballerup, Denmark;

Jensen, Peter Møller, a citizen of Denmark, residing at Svenstrupvej 6, DK-2970 Hørsholm, Denmark; and

Jensen, Jens Møller, a citizen of Denmark, residing at Nyhavn 37, DK-1051

København K, Denmark

for application entitled: Medical Device.

The provisional application contains:

- 12 pages of specification
- 2 sheets of drawings

Address all future communications to Steve T. Zelson, Esq., Novo Nordisk of North America, Inc., 405 Lexington Avenue, Suite 6400, New York, NY 10174-6401.

Please charge the required fee, estimated to be \$150, to Novo Nordisk of North America, Inc., Deposit Account No. 14-1447. A duplicate of this sheet is enclosed.

Respectfully submitted,

Date: September 1, 1998

Elias J. Lambiris, Reg. No. 33,728 Novo Nordisk of North America, Inc. 405 Lexington Avenue, Suite 6400 New York, NY 10174-6401

(212) 867-0123

Attorney Dkl 7: 5533.003-45

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The present invention relates to a medication delivery device having a cartridge assembly and a dosing assembly coupled together for delivering selected doses of medication.

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#### Background

Some medication, such as insulin is self-administered. The typical diabetes patient will require injections of insulin several times during the day. The required insulin dose will vary from patient to patient, and will for each patient often also vary during the day. Each patient will often establish a regimen for the insulin administration adjusted to his or her insulin need as well as lifestyle. Medication delivery pens have been developed to facilitate the self-administration of medication, such as insulin.

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One prior art medication delivery pen includes a pen body assembly comprising a medication cartridge and a plunger device. A needle assembly may be connected to the pen body assembly. The medication is delivered by moving or pressing a plunger in the direction of the needle assembly thereby delivering the medication. When the medication in the cartridge is exhausted the pen body assembly is discarded. Depending on the medication needs for each individual the medication in the cartridge will last for several days. During this period the needle assembly will often have to be displaced by a new assembly or new needle due to increasing bluntness of the needle making injections painful for the patient.

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Due to the environmental and economical reasons medication delivery pens were developed, for which pens only a part of the pen was discarded after medication exhaustion, such as the cartridge only.

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An example of prior art pens is disclosed in EP 0 688 571 wherein a medication delivery pen has a reusable pen body assembly and a disposable cartridge assembly that are threadedly engageable with one another. The disposable cartridge assembly includes a plunger and can releasably receive a needle cannula assembly through a threaded coupling. A driving means in the pen body assembly engages the plunger after engagement of the pen body assembly and the cartridge assembly, whereby the pen is ready for dosing the medicine within the cartridge. The cartridge

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holder assembly can be disassembled from the pen body assembly after the medication therein has been exhausted, discarded and replaced.

However, a drawback of the above-mentioned pen is that the driving means of the pen body may be disengaged from the plunger of the cartridge during normal use resulting in inaccurate dosing of the medicine.

For the device disclosed in EP 0 688 571, the needle assembly will often have to be replaced independently of replacement of the cartridge. When releasing the needle assembly from the cartridge assembly the cartridge assembly may inadvertently be released or partly released from the pen body assembly. Thereby the driving means of the pen body may be disengaged from the plunger of the cartridge. In particular if the pen body assembly is only partly released from the cartridge assembly the user will most probably not be aware of the disengagement but will receive only a portion or even nothing of the medicine.

Even pens with differently pitched threaded couplings and/or threaded couplings having different diameters whereby the force exerted to fasten and/or release one coupling is greater than the force necessary for the other coupling present this problem. It is easy to imagine that a small obstruction (a sandskorn, for example) to the smoothest going coupling will necessitate a greater force to fasten/release that coupling which force tends towards the force necessary for the other coupling.

Accordingly, it is an object of the present invention to provide a medication delivery device with which the inadvertent disengagement of the driving means and plunger means from the plunger or stopper in the cartridge is avoided.

#### Summary of the invention

According to a first aspect of the invention a medication delivery device is provided which comprises

a cartridge assembly, having one end sealed with a pierceable sealing, said end of the cartridge assembly comprising coupling means for releasably mounting a needle

assembly, and comprising a cartridge having a stopper adapted to receive plunger means,

a dosing assembly comprising plunger means,

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and optionally a needle assembly,

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wherein the cartridge assembly and the dosing assembly are coupled together, and the device further comprises means for securing that the plunger means abuts on the stopper during use of the device.

In a preferred embodiment the dosing assembly is reusable and the cartridge assembly is disposable, and accordingly, a second aspect of the present invention is a medication delivery device wherein the dosing assembly is releasably coupled to the cartridge assembly.

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By the term "use of the device" is meant the normal use, including measuring and delivering the medication, removing a cap from the cartridge assembly and/or needle as well as attaching and releasing the needle assembly. It is understood that the plunger means must disengage the stopper when the cartridge assembly is deliberately released from the dosing assembly because the medication in the cartridge has been exhausted and the cartridge assembly is to be discarded. In this situation the plunger means is to be retracted to the dosing assembly before assembling the device with a new cartridge assembly.

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Securing the abutment of the plunger means on the stopper during use of the medication delivery device, in particular when the needle assembly is coupled to and/or decoupled from the cartridge assembly, may be carried out by a variety of means. In a preferred embodiment the abutment is secured by preventing the cartridge assembly from being inadvertently released from the dosing assembly.

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Furthermore, it is a preferred aspect of the invention to provide a medication delivery device, which device is arranged for securing that the plunger means abuts on the stopper during coupling and/or decoupling of the needle assembly.

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In one embodiment of the invention the dosing assembly is coupled to the cartridge assembly at the end of the cartridge assembly opposite the means for mounting the needle assembly, and the plunger means is a rod element adapted to exert an axial movement of the stopper towards the sealed end of the cartridge.

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Accordingly, it is an aspect of the present invention to provide a medication delivery device, wherein the means for coupling the dosing assembly and the cartridge assembly together are such that the coupling and/or decoupling of the needle assembly does not cause an axial movement of the cartridge assembly with respect to the dosing assembly. In this way it is assured that the rod element does not disengage the stopper in the cartridge when the user attaches the needle assembly or removes it after use. Thereby the user can be confident of the accuracy of the dosage selected.

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The means for coupling the dosing assembly and the cartridge assembly together may be any suitable coupling, preferably a releasable coupling. Examples of the coupling are snap locks, such as snap locks with guidewire and sideways snap locks, snap locks released through threads, bajonet locks, luer locks, hinged locks, threaded locks and any suitable combinations thereof.

In particular, when the cartridge assembly is released from the dosing assembly

through a movement including an axial movement, such as through a threaded coupling, it is preferred that the means for releasably coupling the needle assembly and the cartridge assembly together are such that the coupling and/or decoupling of the needle assembly cannot cause an axial movement of the cartridge assembly with respect to the dosing assembly. Thus, in that respect examples of the preferred couplings between the needle assembly and the cartridge assembly include releasable snap locks. Another preferred embodiment includes a safety on the coupling between the dosing assembly and the cartridge assembly, such as hinge on the coupling or a threaded coupling releasable only after exerting an axial pressure on

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According to the invention preferred combinations of couplings between the dosing assembly and the cartridge assembly and between the needle assembly and the cartridge assembly, respectively, are a threaded coupling combined with a snap

coupling, a bajonet lock or a luer lock combined with a snap lock, or a snap lock combined with a snap lock, or any other combination for which the couplings are independently working.

Another aspect of the present invention is a cartridge assembly for use in the medication delivery device according to the invention. The cartridge assembly comprises a cartridge for the medication to be delivered. The cartridge assembly has one end sealed with a pierceable sealing, said end of the cartridge assembly comprising coupling means for releasable mounting a needle assembly, and another end comprising coupling means adapted to engage a dosing assembly. Furthermore, the cartridge comprises a stopper.

The cartridge assembly may further comprise a housing for protecting at least a part of the cartridge assembly.

In a preferred embodiment at least one of the coupling means of the cartridge assembly is unitarily moulded with the cartridge, and in a more preferred embodiment all the coupling means are unitarily moulded with the cartridge. In the latter case the cartridge assembly may be comprised of just one part, i.e. the cartridge including the coupling means.

#### **Drawings**

Fig. 1 is an exploded perspective view of the medication delivery device.

Fig. 2 is a cross-sectional view showing part of the medication delivery device, 2a immediately after assembling before the first injection, and 2b after some time of use.

Fig. 3 is a cross-sectional view showing the cartridge before assembling of the medication delivery device.

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#### Detailed description of the invention

A medication delivery device in accordance with the present invention is identified generally by the numeral 20 in Fig. 1 and 2. Medication delivery device 20 includes a dosing assembly 6, and cartridge assembly 1, a needle assembly 16 and a cap 14.

The dosing assembly 6 is illustrated in Fig. 1 and 2. It is understood, however, that the dosing assembly 6 according to the invention may be any suitable dosing unit including plunger means, and accordingly, that variations from the depicted embodiment may be provided, and are considered to be within the scope of this invention. In the depicted embodiment the dosing assembly 6 includes a cylindrical housing surrounding the plunger means 17 of the dosing unit and having opposed proximal and distal ends.

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In one aspect of the invention the plunger means comprises a rod element 7 which is adapted to engage the stopper 4 of the cartridge assembly 1. The rod element 7 advances axially into the cartridge 5 during injections. The dosing assembly may have any suitable driving means for advancing the rod element 7.

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The dosing unit 6 preferably also comprises scale means 10 indicating the dosing quantity selected by activating the dose setting means 9 for defining specified selected doses of medication to be delivered. The selected dose may be delivered by actuating the actuator button 18. The actuator button is part of the driving means of the dosing assembly exerting its force on the rod element 7.

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The dosing assembly further comprises coupling means 8 adapted for engagement with the cartridge assembly. The coupling means 8 may be internal or external couplings. In a preferred embodiment the coupling 8 is an internal coupling.

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The cartridge assembly 1 is illustrated in Fig. 1 and 2, and in greater detail in Fig. 3. In Fig. 1 cartridge assembly 1 includes a moulded cartridge 5 extending from proximal end 21 to distal end 22.

At the distal end 22 of the cartridge assembly 1 is provided coupling means 2 for releasably mounting a needle assembly 11. At the proximal end 21 of the cartridge assembly 1 is provided coupling means 3 for mounting a dosing assembly 6. The coupling means are as described above.

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Cartridge 5 also comprises a stopper 4 in sliding fluid tight engagement within said cartridge 5. The stopper 4 is adapted to receive the plunger means, such as a rod element 7 of the dosing assembly 6.

The cartridge assembly 1 may further comprise a housing for protecting some or all of the cartridge 5. When the cartridge assembly 1 includes a housing, one or both of the couplings 2, 3 of the cartridge may be moulded unitarily with the housing.

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In a preferred embodiment at least one of the couplings 2, 3 is moulded unitarily with the cartridge 5, minimising the total number of parts of the device and thereby the production costs.

Instead of the protective housing the cartridge 5 may have integrally moulded reinforcements of the cartridge wall.

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The depicted cartridge 5 is cylindrical having couplings 2, 3 at opposed ends. However, the cartridge may obtain any suitable form and the cross-section may be circular or non-circular, such as substantially triangular or oval.

25 In Fig. 1 and Fig. 2 the couplings 2, 3 are opposing each other. However, coupling 2 being separate from coupling 3 may be arranged in any angle with respect to coupling 3.

A suitable choice of material allows the cartridge to be at least partly transparent, whereby the user can see whether liquid is left in the cartridge.

Referring to Fig. 3 the coupling means of the cartridge are shown in greater detail. The coupling means 3 is an external thread, whereas the coupling means 2 is a recess for a snap lock of the needle assembly. Both coupling means are moulded unitarily with the cartridge.

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The device according to the invention may include a protective cap 14 that is removably mounted over the cartridge assembly 1 and/or the needle 11 and which is removed before injection of the medication in the cartridge 5. The cap further ensures that the content of the cartridge is protected against sunlight.

The various parts of the medication delivery device are advantageously made of plastics, e.g. by injection moulding.

The medication delivery device 20 may further comprise any appropriate needle assembly 11, such as a double ended needle 13 having opposed proximal and distal points and a lumen extending axially therebetween.

A mounting hub 12 is engaged on the needle 13 and is removably connected to the coupling means 2 at the needle end of the cartridge assembly. The relative location of the mounting hub 12 ensures that the proximal point of the needle 13 will pierce the sealing when the mounting hub 12 is engaged with the coupling means 2 on the cartridge assembly 1.

The needle assembly 11 may further comprise a removable shield or cap 15 for protecting against accidental needle sticks.

The device according to the invention is suitable for delivering pre-set dosages of insulin, it is however understood that the device is suitable for the injection of pre-set dosages of other liquids.

In use the user will set the dose by means of the dose setting means 9. Before activating the actuator button 18 the cap 14 must be removed from the cartridge assembly 1 whereby the device 20 is prepared for an injection. The injection is effected by activating the actuator button 18, which again will effect the stopper 4 to be moved towards the needle at the sealed end 22 of the cartridge 5, thereby delivering the desired pre-set dosage. A subsequent dosage of medication will be set in exactly the same manner as described above. However, for such a subsequent dosage, the rod element 7 and the stopper 4 will be in a partly advanced position as

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starting point. Dose setting and injections can be carried out until all of the medica tion has been used.

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#### Claims:

- 1. A medication delivery device comprising
- a cartridge assembly, having one end sealed with a pierceable sealing, said end of the cartridge assembly comprising coupling means for releasably mounting a needle assembly, and comprising a cartridge having a stopper adapted to receive plunger means,
- 10 a dosing assembly comprising plunger means,

and optionally a needle assembly,

wherein the cartridge assembly and the dosing assembly are coupled together, and the device further comprises means for securing that the plunger means abuts on the stopper during use of the device.

- A medication delivery device according to claim 1, wherein the dosing assembly is releasably coupled to the cartridge assembly.
- A medication delivery device according to any of the preceding claims, wherein the device is arranged for securing that the plunger means abuts on the stopper during coupling and/or decoupling of the needle assembly.
- 4. A medication delivery device according to any of the preceding claims, wherein the plunger means comprises a rod element adapted to exert an axial movement of the stopper towards the sealed end of the cartridge.
  - 5. A medication delivery device according to any of the preceding claims, wherein the means for releasably coupling the dosing assembly and the cartridge assembly together are such that the coupling and/or decoupling of the needle assembly does not cause an axial movement of the cartridge assembly with respect to the dosing assembly.

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- A medication delivery device according to any of the preceding claims, wherein the dosing assembly is released from the cartridge assembly through a movement including an axial movement.
- A medication delivery device according to claim 6, wherein the dosing assembly is released from the cartridge assembly through a threaded coupling.
  - 8. A medication delivery device according to any of the preceding claims, wherein the dosing assembly comprises scale means.
  - A medication delivery device according to any of the preceding claims, wherein the dosing assembly comprises dose setting means for defining specified selected doses of medication to be delivered.
- 15 10. A medication delivery device according to any of the preceding claims, wherein the cartridge assembly comprises a housing.
  - 11. A medication delivery device according to any of the preceding claims, wherein the cartridge is unitarity moulded with at least one coupling means.
  - 12. A medication delivery device according to any of the preceding claims, further comprising a cap for protecting the needle assembly and/or the cartridge assembly.
- 25 13. A cartridge assembly for use in the medication delivery device as claimed in any of claims 1-12, having one end sealed with a pierceable sealing, said end of the cartridge assembly comprising coupling means for engaging a needle assembly, and another end comprising coupling means adapted to engage a dosing assembly, further comprising a cartridge said cartridge comprising a slidable stopper.
  - 14. A cartridge assembly according to claim 13, further comprising a housing.
  - 15. A cartridge assembly according to claim 13 or 14, wherein the cartridge is unitarily moulded with at least one coupling means.

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- 16. A cartridge assembly according to any of claims 13-15, wherein the coupling means adapted to engage the dosing unit is such that coupling and/or decoupling of the needle assembly does not cause an axial movement of the cartridge
- 5 assembly with respect to the dosing assembly.
  - 17. A cartridge assembly according to any of claims 13-16, wherein the dosing assembly is released from the cartridge assembly through a movement including an axial movement.

18. A cartridge assembly according to claim 17, wherein the dosing assembly is released from the cartridge assembly through a threaded coupling.

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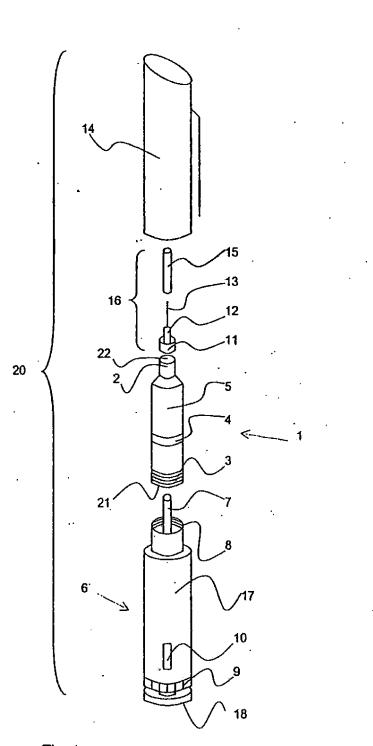


Fig. 1

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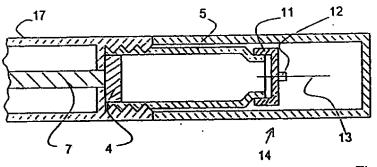


Fig. 2 a

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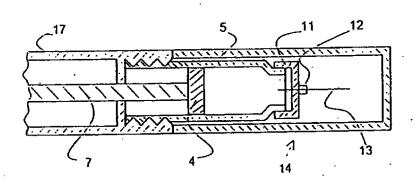
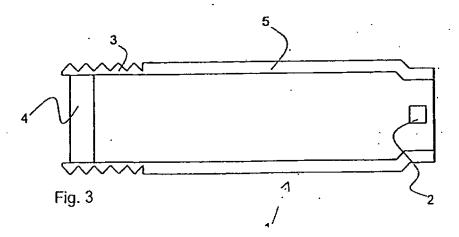


Fig. 2 b



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(12) United States Patent Buch-Rasmussen et al.

US 6,582,408 B1 (10) Patent No.: (45) Date of Patent: Jun. 24, 2003

(54)	MEDICAL DEVICE			
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(*)	Notice:	Subject to any disclaimer, the term of this		

kd or adjusted under 35 U.S.C. 154(b) by 0 days.

(21) Appl. No.: 09/349,748 (22) Filed: Jul 4, 1999

Related U.S. Application Data Provisional application No. 60/098,707, filed on Sep. 1, Foreign Application Priority Data

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(51)	Int. Cl.7		A61M 5/80
(52)	U.S. CL	604	/232; 604/187
(58)	Field of Scare	ch	604/186, 187,
	6	04/232, 188, 192, 195, 1	207-218, 200,
	•	201.	228, 233, 234

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0 702 970 A2 3/1996

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WO WO WO WO WO	WO 93/00948 WO 94/21213 WO 95/13842 0 688 571 A1 WO 96/0230 WO 97/46620 WO 99/16487	1/1993 9/1994 5/1995 12/1995 2/1996 12/1997 4/1999		DO not

Abstract of Australian patent application AU-A-73 632/81.

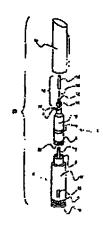
\* cited by examiner

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**(57)** ABSTRACT

The present invention relates to a medicatio adelivery device comprising a cartaidge assembly, a during assembly and optionally a needle assembly. The cartridg: assembly comprises a cartridge having a stopper adapted to receive a planger. Furthermore, the cartridge assembly has one and sealed with a pierce able scaling, said end comprising coupling device for engaging a needle assumbly, and another end comprising coupling device for cataging the dosing assembly. The dosing assembly comprises a plunger and has coupling device for engaging the cartidg: assembly. The extridge assembly and the desing assembly are coupled together for delivering scienced dosos of medication. The device further comprises mechanism for recuring that the planger abuts on the stopper during use of the device, in particular when the desire assembly is releasable coupled to the cartridge assembly. The securing mest anism is preferably a mechanism for preventing the cactridge assembly from being inadvertently released from the closing assembly. The certaidge is preferably moided from a plastic meterial, such as a transparent material, and may be housed in a cartridge housing for protection of the cartridge. The medi-cation delivery device is especially suitable for delivering insulin, growth hormone or the like medic nes.

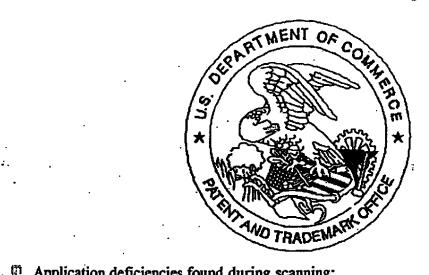
11 Claims, 2 Drawing Sheets





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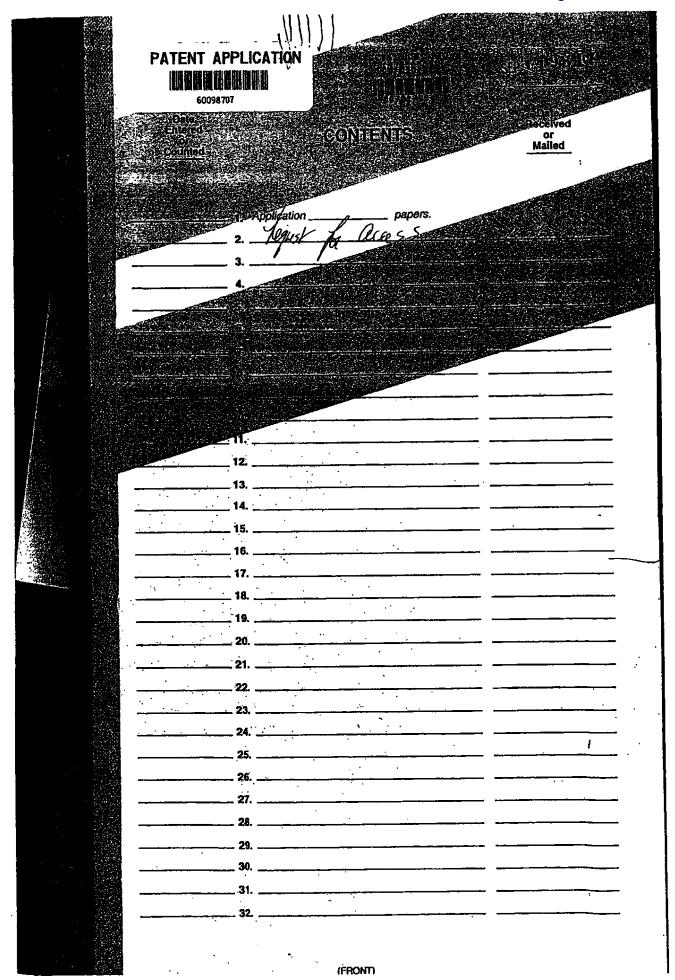
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# EXHIBIT 5



## Kongeriget Danmark

**PRIORITY DOCUMENT** 

Patent application No:

PA 1998 01501

Date of filing:

17 November 1998

Applicant:

Novo Nordisk A/S

Novo Allé

DK-2880 Bagsværd

This is to certify the correctness of the following information:

The attached photocopy is a true copy of the following document:

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Patent- og Varemærkestyrelsen **Erhvervsministeriet** 

TAASTRUP 26 November 1999

Head Clerk

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The present invention relates to a medication delivery device having a cartridge assembly and a dosing assembly coupled together for delivering selected doses of medication.

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#### Background

Some medication, such as insulin is self-administered. The typical diabetes national will require injections of insulin several times during the day. The required insulin dose will vary from patient to patient, and will for each patient often also vary during the day. Each patient will often establish a regimen for the insulin administration adjusted to his or her insulin need as well as illestyle. Medication delivery pens have been developed to facilitate the self-administration of medication, such as insulin.

- One prior art medication delivery pen includes a pen body assembly comprising a 15 medication cartridge and a plunger device. A needle assembly may be connected to the pen body assembly. The medication is delivered by moving or pressing a plunger in the direction of the needle assembly thereby delivering the medication. When the medication in the cartridge is exhausted the pen body assembly is dis-20 carded. Depending on the medication needs for each individual the medication in the cartridge will last for several days. During this period the needle assembly will often have to be displaced by a new assembly or new needle due to increasing bluntness of the needle making injections painful for the patient.
- 25 Due to the environmental and economical reasons medication delivery pens were developed, for which pens only a part of the pen was discarded after medication exhaustion, such as the carridge only
  - An example of prior an pens is disclosed in EP 0 668 571 wherein a medication delivery pen has a reusable pen body assembly and a disposable cartridge assembly that are threadedly engageable with one another. The disposable cariridge assembly includes a plunger and can releasably receive a needle cannula assembly through a threaded coupling. A driving means in the pen body assembly engages the plunger after engagement of the pen body assembly and the cartridge assembly. whereby the pen is ready for dosing the medicine within the cartridge. The cartridge

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holder assembly can be disassembled from the pen body assembly after the medication therein has been exhausted, discarded and replaced

However, a drawback of the above-mentioned pan is that the driving means of the pen body may be disengaged from the plunger of the carridge during normal use resulting in inaccurate dosing of the medicine.

For the device disclosed in EP 0 586 571, the needle assembly will often have to be replaced independently of replacement of the cartridge. When releasing the needle essembly from the cartridge assembly the cartridge assembly may inadvertently be released or parily released from the pen body assembly. Thereby the driving means of the pen body may be disengaged from the plunger of the cartridge. In particular if the pen body assembly is only parity released from the cartridge assembly the user witi most probably not be aware of the disengagement but will receive only a portion or even nothing of the medicine

Even pens with differently pitched threaded couplings and/or threaded couplings having different diameters whereby the force exerted to faster and/or release one coupling is greater than the force necessary for the other coupling present this problem. It is easy to imagine that a small obstruction (a sandskom, for example) to the smoothest going coupling will necessitate a greater force to fasten/release that coupling which force tends towards the force necessary for the other coupling.

Accordingly, it is an object of the present invention to provide a medication delivery device with which the inadvertent disengagement of the driving means and plunger means from the plunger or stopper in the cartridge is avoided.

#### Summary of the invention

According to a first aspect of the invention a medication delivery device is provided which comprises

a cartridge assembly, having one end sealed with a pierceable sealing, said and of the cartridge assembly comprising coupling means for releasably mounting a needle

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assembly, and comprising a cartridge having a stopper adapted to receive plunger means.

a dosing assembly comprising plunger means,

and optionally a needle assembly.

wherein the cartridge assembly and the dosing assembly are coupled together, and the device further comprises means for securing that the plunger means abuts on the stopper during use of the device.

in a preferred embodiment the dosing assembly is reusable and the cartridge assembly is disposable, and accordingly, a second aspect of the present invention is a medication delivery device wherein the dosing assembly is releasably coupled to the cartridge assembly.

By the term "use of the device" is meant the normal use, including measuring and delivering the medication, removing a cap from the cartridge assembly and/or necdie as well as attaching and releasing the needle assembly. It is understood that the plunger means must disengage the stopper when the cartridge assembly is deliberately released from the dosing assembly because the medication in the cartridge has been exhausted and the cartridge assembly is to be discarded. In this altuation the plunger means is to be retracted to the dosing assembly before assembling the device with a new cartridge assembly.

Securing the abutment of the plunger means on the stopper during use of the medication delivery device, in particular when the needle essembly is coupled to and/or decoupled from the cartridge assembly, may be carried out by a variety of means. In a preferred embodiment the abutment is secured by preventing the cartridge assembly from being inadvertently released from the dosing assembly.

Furthermore, it is a preferred aspect of the invention to provide a medication delivery device, which device is arranged for securing that the plunger means abute on the Stopper during coupling and/or decoupling of the needle assembly

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In one embodiment of the invention the dosing assembly is coupled to the cartridge assembly at the end of the cartridge assembly opposite the means for mounting the needle assembly, and the plunger means is a rod element adapted to exert an axial movement of the stopper towards the sealed and of the cartridge.

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Accordingly, it is an aspect of the present invention to provide a medication delivery device, wherein the means for coupling the dosing assembly and the cartridge assembly together are such that the coupling and/or decoupling of the needle assembly does not cause an axial movement of the cartridge assembly with respect to the dosing assembly. In this way it is assured that the rod element does not disengage the stopper in the cartridge when the user attaches the needle assembly or removes It after use. Thereby the user can be confident of the accuracy of the dosage selected.

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The means for coupling the dosing assembly and the carridge assembly together may be any suitable coupling, preferably a releasable coupling. Examples of the coupling are snap locks, such as snap locks with guidewire and sideways snap locks, snap locks released through threads, bajonet locks, luer locks, hinged locks, threaded locks and any suitable combinations thereof.

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in particular, when the cartridge assembly is released from the dosing assembly through a movement including an axial movement, such as through a threaded coupling, it is preferred that the means for releasably coupling the needle assembly and the cartridge assembly together are such that the coupling and/or decoupling of the needle assembly cannot cause an axial movement of the cartridge assembly with respect to the dosing assembly. Thus, in that respect examples of the preferred couplings between the needle assembly and the cartridge assembly include releasable snap locks. Another preferred embodiment includes a safety on the coupling between the dosing assembly and the cartridge assembly, such as hinge on the coupling or a threaded coupling releasable only after exerting an axial pressure on the coupling.

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According to the Invention preferred combinations of couplings between the dosing assembly and the cartridge assembly and between the needle assembly and the cartridge assembly, respectively, are a threaded coupling combined with a snap

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coupling, a bajonat lock or a lust lock combined with a snap lock, or a snap lock combined with a snap lock, or any other combination for which the couplings are independently working.

Another aspect of the present invention is a cartridge assembly for use in the medication delivery device according to the invention. The cartridge assembly comprises a cartridge for the medication to be delivered. The cartridge assembly has one end sealed with a pierceable seating, said end of the cartridge assembly comprising coupling means for releasable mounting a needle assembly, and another end comprising coupling means adapted to engage a dosing assembly. Furthermore, the cartridge comprises a stopper.

The cartridge assembly may further comprise a housing for protecting at least a part of the cartridge assembly.

In a preferred embodiment at least one of the coupling means of the cartridge assembly is unitarily moulded with the cartridge, and in a more preferred embodiment all the coupling means are unitarily moulded with the cartridge in the latter case the cartridge assembly may be comprised of just one part, i.e. the cartridge including the coupling means.

In another embodiment the Invention relates to a medication delivery device for transferring medication from the cartridge into a syringe with a needle. In this embodiment the coupling means for engaging the needle assembly may be replaced by coupling means for engaging the syringe, or coupling means for both may be provided. The coupling means may be a syringe holder, for example a cylinder coupled to the cartridge comprising a central bore for receiving the syringe. The syringe is coupled to the cartridge having the needle piercing the sealing. By activation of the dosing means the metered amount of medication is driven into the syringe. The syringe is then ready for injection after being removed from the cartridge.

#### Drawings

Fig. 1 is an exploded perspective view of the medication delivery device.

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Fig. 2 is a cross-sectional view showing part of the medication delivery device, 2e immediately after assembling before the first injection, and 2b after some time of use

Fig. 3 is a cross-sectional view showing the cardidge before assembling of the medication delivery device.

#### Detailed description of the invention

- A medication delivery device in accordance with the present invention is identified 10 generally by the numeral 20 in Fig. 1 and 2. Medication delivery device 20 includes a dosing assembly 6, and cartridge assembly 1, a needle assembly 16 and a cap 14.
- The dosing assembly 6 is illustrated in Fig. 1 and 2. It is understood, however, that the dosing assembly 6 according to the invention may be any suitable dosing unit including plunger means, and accordingly, that variations from the depicted embodiment may be provided, and are considered to be within the scope of this invention. In the depicted embodiment the dosing assembly 6 includes a cylindrical housing surrounding the plunger means 17 of the dosing unit and having opposed 20 proximal and distal ends

In one aspect of the invention the plunger means comprises a rod element 7 which is adapted to engage the stopper 4 of the cartridge assembly 1. The rod element 7 advances axially into the cartridge 5 during injections. The dosing assembly may have any suitable driving means for advancing the rod element 7.

The dosing unit 6 preferably also comprises scale means 10 indicating the dosing quantity selected by activating the dose setting means 9 for defining specified selected doses of medication to be delivered. The selected dose may be delivered by actuating the actuator button 18. The actuator button is part of the driving means of the dosing assembly exerting its force on the rod element 7.

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The dosing assembly further comprises coupling means 8 adapted for engagement with the cartridge assembly. The coupling means 8 may be internal or external couplings. In a preferred embodiment the coupling 8 is an internal coupling.

The cartridge assembly 1 is illustrated in Fig. 1 and 2, and in greater detail in Fig. 3. in Fig. 1 cartridge assembly 1 includes a moulded cartridge 5 extending from proximai end 21 to distal end 22.

At the distal end 22 of the cartridge assembly 1 is provided coupling means 2 for releasably mounting a needle assembly 11. At the proximal and 21 of the certridge assembly 1 is provided coupling means 3 for mounting a dosing assembly 6. The coupling means are as described above

Cartridge 5 also comprises a stopper 4 in sliding fluid tight engagement within said 15 cartridge 5. The stopper 4 is adapted to receive the plunger means, such as a rod element 7 of the dosing assembly 6

The cartridge assembly 1 may further comprise a housing for protecting some or all of the cartridge 5. When the cartridge assembly 1 includes a housing, one or both of the couplings 2, 3 of the certridge may be moulded unitarily with the housing.

in a preferred embodiment at least one of the couplings 2, 3 is moulded unitarity with the cartridge 5, minimising the total number of parts of the device and thereby the production costs.

Instead of the protective housing the cartridge 5 may have integrally moulded reinforcements of the cartridge wall

The depicted cartridge 5 is cylindrical having couplings 2, 3 at opposed ends. However, the cartridge may obtain any suitable form and the cross-section may be cir-30 cular or non-circular, such as substantially triangular or oval.

In Fig. 1 and Fig. 2 the couplings 2, 3 are opposing each other. However, coupling 2 being separate from coupling 3 may be arranged in any angle with respect to coupling 3

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A suitable choice of malarisi allows the cartridge to be at least partly transparent, whereby the user can see whether liquid is left in the cartridge.

- 5 Referring to Fig. 3 the coupling means of the cartridge are shown in greater detail.
  The coupling means 3 is an external thread, whereas the coupling means 2 is a recess for a snap lock of the needle assembly. Both coupling means are moulded unitarily with the cartridge.
- 10 The device according to the Invention may include a protective cap 14 that is removably mounted over the cariridge assembly 1 and/or the needle 11 and which is removed before injection of the medication in the cartridge 5. The cap further ensures that the content of the cartridge is protected against sunlight.
- 15 The various parts of the medication delivery device are advantageously made of plastics, a p. by injection moulding.

The medication delivery device 20 may further comprise any appropriate needle assembly 11, such as a double ended needle 13 having opposed proximal and distall points and a luman extending axially therebetween.

A mounting hub 12 is engaged on the needle 13 and is removably connected to the coupling means 2 at the needle end of the cartridge assembly. The relative location of the mounting hub 12 ensures that the proximal point of the needle 13 will pierce the sealing when the mounting hub 12 is engaged with the coupling means 2 on the cartridge assembly 1.

The needle assembly 11 may further comprise a removable shield or cap 15 for protecting against accidental needle sticks.

The device according to the invention is suitable for delivering pre-set dosages of insulin, it is however understood that the device is suitable for the injection of pre-set dosages of other liquids.

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In use the user will set the dose by means of the dose setting means 9. Before activating the actuator button 18 the cap 14 must be removed from the cartridge assembly 1 whereby the device 20 is prepared for an injection. The injection is effected by activating the actuator button 18, which again will effect the stopper 4 to be moved towards the needle at the sealed and 22 of the cartridge 5, thereby defivering the desired pre-set dosage. A subsequent dosage of medication will be set in exactly the same manner as described above. However, for such a subsequent dosage, the rod element 7 and the stopper 4 will be in a parity advanced position as starting point. Dose setting and injections can be carried out until all of the medication has been used.

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#### Claims:

- 1. A medication delivery device comprising
- a cartridge assembly, having one end sealed with a pierceable sealing, said end 5 of the cartridge assembly comprising coupling means for releasably mounting a needle assembly, and comprising a cartridge having a slopper adapted to receive plunger means,
- a dosing assembly comprising plunger means, 10

and optionally a needle assembly,

- wherein the cartridge assembly and the dosing assembly are coupled together, 15 and the device further comprises means for securing that the plunger means abuts on the stopper during use of the device.
  - 2. A medication delivery device according to claim 1, wherein the dosing assembly is releasably coupled to the cartridge assembly.

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- 3. A medication delivery device according to any of the preceding dalms, wherein the device is arranged for securing that the plunger means abuts on the stopper during coupling and/or decoupling of the needle assembly.
- 25 4. A medication delivery device according to any of the preceding claims, wherein the plunger means comprises a rod element adapted to exert an axial movement of the stopper lowards the sealed end of the cartridge.
- 5 A medication delivery device according to any of the preceding claims, wherein 30 the means for releasably coupling the dosing assembly and the cartridge assembly together are such that the coupling and/or decoupling of the needle assembly does not cause an axial movement of the cartridge assembly with respect to the dosing ascembly.

HEIDEN & HOLDERG + 43596001 NR. 023 16:29 17/11/98 11 6. A medication delivery device according to any of the preceding claims, wherein the dosing assembly is released from the cartridge assembly through a movement including an axial movement 7. A medication delivery device according to claim 8, wherein the dosing assembly 5 is released from the cariridge assembly through a threaded coupling. 8. A medication delivery device according to any of the preceding claims, wherein the dosing assembly comprises scale means. 10 9 A medication delivery device according to any of the preceding claims, wherein the dosing assembly comprises dose setting means for defining specified selected doses of medication to be delivered. 10. A medication delivery device according to any of the preceding claims, wherein 15 the cartridge assembly comprises a housing 11. A medication delivery device according to any of the preceding claims, wherein the cartridge is unitarily moulded with at least one coupling means. 20 12. A medication delivery device according to any of the preceding claims, further comprising a cap for protecting the needle assembly and/or the cartridge assembly. 13. A cartridge assembly for use in the medication delivery device as claimed in any 25 of claims 1-12, having one end sealed with a pierceable scaling, said and of the cartridge assembly comprising coupling means for engaging a needle assembly, and another end comprising coupling means adapted to engage a dosing assambly, further comprising a cartridge said certridge comprising a slidable stop-30 per. 14. A cartridge assembly according to claim 13, further comprising a housing. 15. A cartridge assembly according to claim 13 or 14, wherein the cartridge is uni-

tarily moulded with at least one coupling means.

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- 18. A cartridge assembly according to any of claims 13-15, wherein the coupling means adapted to engage the dosing unit is such that coupling and/or decoupling of the needle assembly does not cause an axial movement of the cartridge assembly with respect to the dosing assembly.
- 17 A cartridge assembly according to any of claims 13-16, wherein the dosing assembly is released from the cartridge assembly through a movement including an axial movement.

18 A cartridge assembly according to claim 17, wherein the dosing assembly is released from the cartridge assembly through a threaded coupling.

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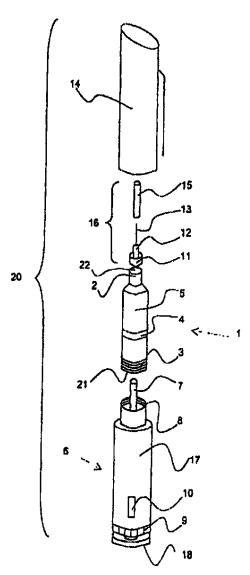


Fig. 1

